

Appendix F Required CC Printed Materials

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F.1 Consent Material

Figure F.1.1
Video Information Handout - WHI Introduction

WOMEN'S HEALTH INITIATIVE INTRODUCTION			
<p>All women begin with a screening process to see if they are eligible (able) to join the study:</p> <ul style="list-style-type: none"> • Health forms • Height, weight, hip, and waist measures • Blood pressure and pulse • Fasting blood test • Other medical tests may be done 			
<p>These screening tests will decide which of the four WHI Programs a woman is able to join:</p>			
<u>Hormone Replacement Program</u>	<u>Dietary Program</u>	<u>Calcium and Vitamin D Program</u>	<u>Observational Program</u>
<ul style="list-style-type: none"> • All women will take one pill daily that either contains hormones or is a placebo (inactive) pill. • All women will attend clinic follow-up visits twice a year. • All women will keep track of symptoms. 	<ul style="list-style-type: none"> • Some women will attend classes to make changes in their eating pattern. • Some will eat as they normally do. • All women will attend clinic follow-up visits once a year. 	<ul style="list-style-type: none"> • Women in either the Hormone or the Dietary Programs may also be able to join the Calcium Program. • All women will take one pill twice daily that either contains calcium and vitamin D or is a placebo. 	<ul style="list-style-type: none"> • All women will complete health questionnaires by mail once a year. • All women will attend a clinic follow-up visit in three years.

Figure F.1.2
Video Information Handout - WHI Dietary Program

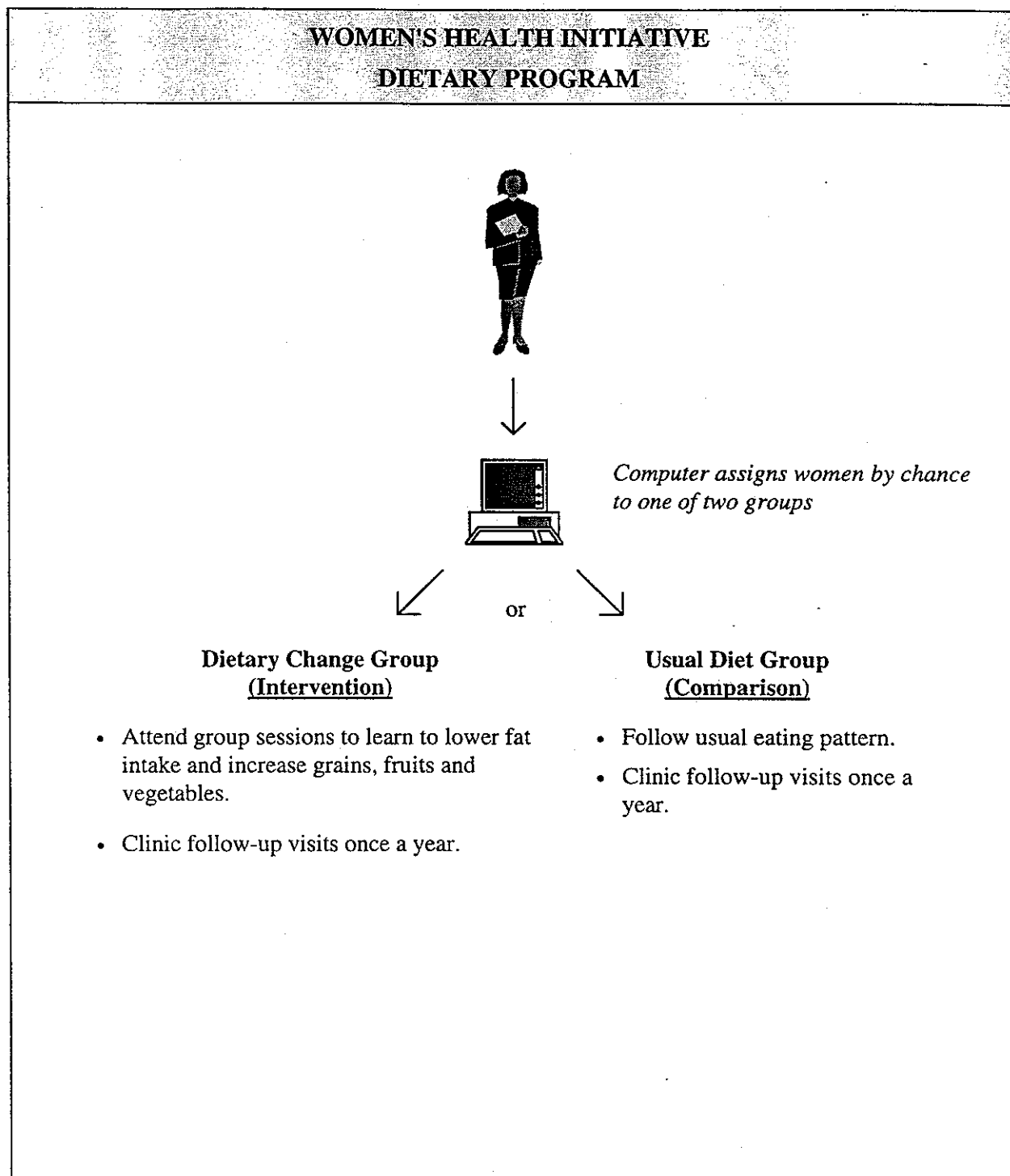


Figure F.1.3
Video Information Handout - WHI Hormone Replacement Program
(For Eligible Women With a Uterus)

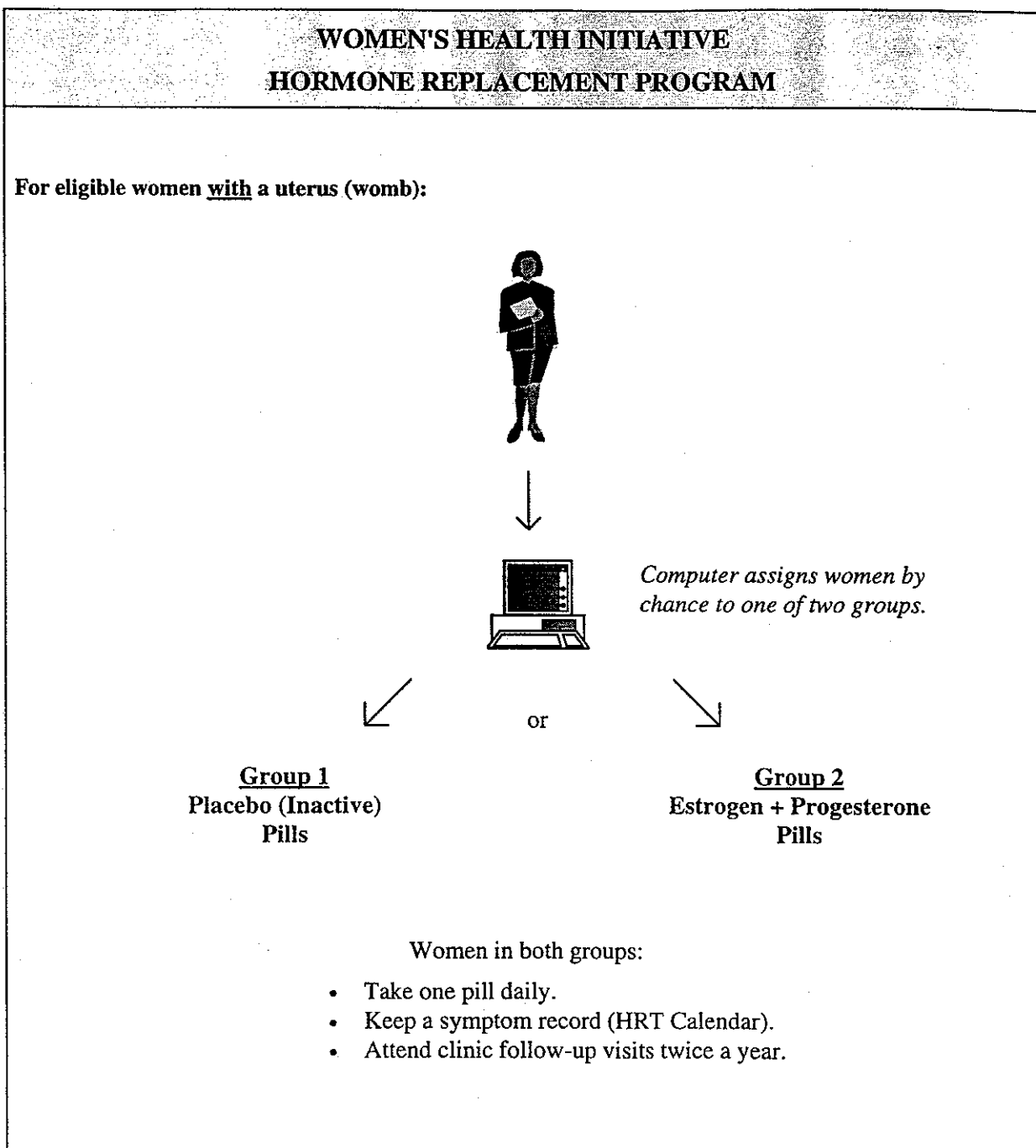
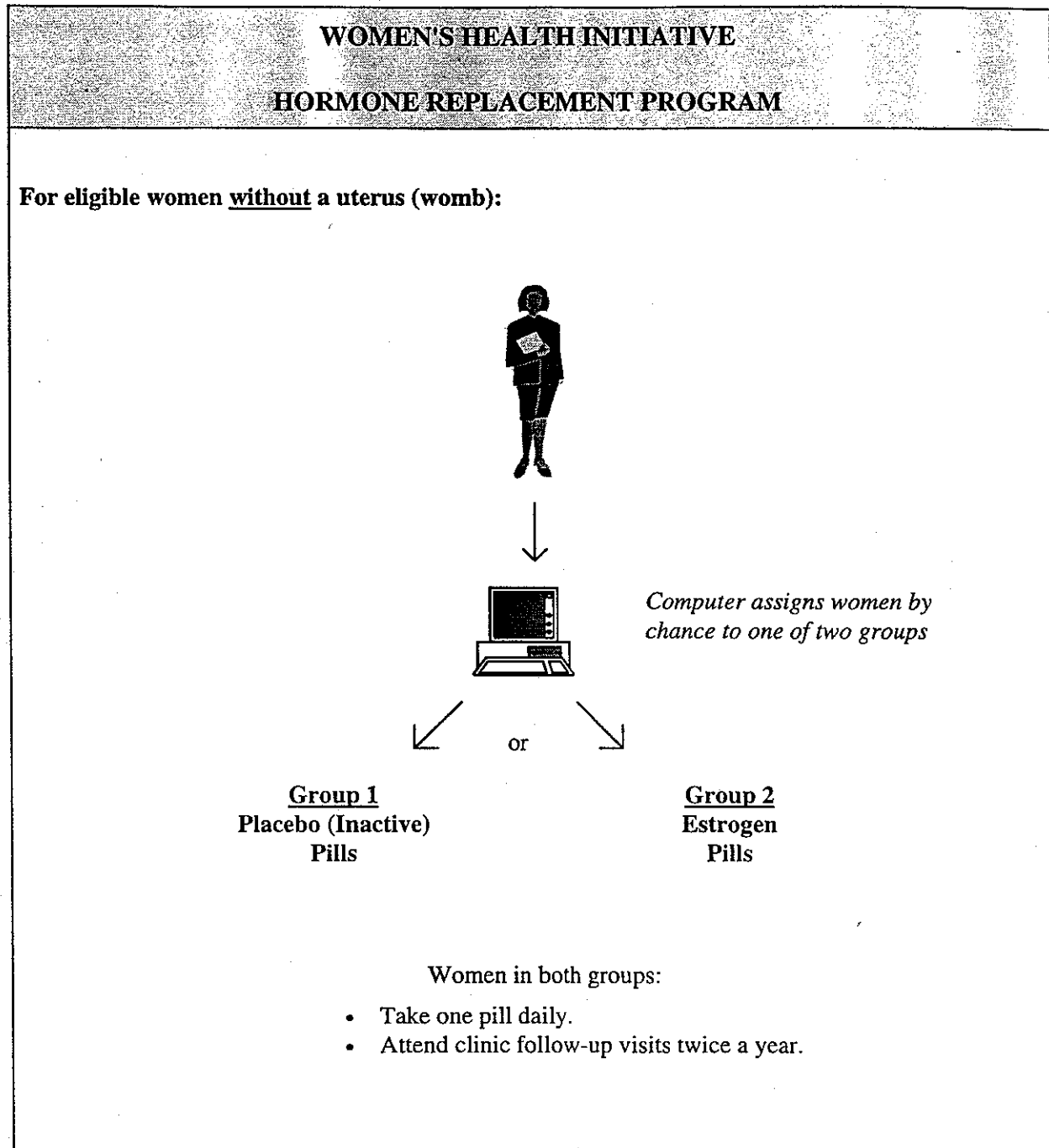


Figure F.1.4
Video Information Handout - WHI Hormone Replacement Program
(For Eligible Women Without a Uterus)



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Figure F2.1.
Welcome to the Women's Health Initiative!

Welcome to the Women's Health Initiative!

The Women's Health Initiative (WHI) is one of the first major studies of women and their health. It will help decide how diet, hormone therapy, and calcium and vitamin D might affect the major causes of death and health problems in women: cancer, heart disease, and broken bones. Being a part of this important project will help us learn more about women's health, and will help doctors find better ways to prevent disease.

Before now, few studies focused on the special health problems of women. This is the first study to examine the health of a very large number of women over a long period of time. About 163,000 women aged 50-79 from centers across the United States will take part in this study.

The WHI is being funded by the National Institutes of Health (NIH), the U.S. Government's medical research agency. The NIH is providing the money to do research that can help women learn how to lead healthier and better lives. This research would not be possible without women like you.



What are the parts of the study?

The WHI is studying how changes in diet, hormone therapy, and calcium and vitamin D might affect women's risk for cancer, heart disease, and broken bones. There are four parts to the study:

- ***Dietary***—In this program, you are asked to follow either your usual eating pattern or an eating program low in fat and high in fruits, vegetables, and grains.
- ***Hormone Replacement***—In this program you are asked to take either hormone pills or inactive pills (placebos).
- ***Calcium and Vitamin D***—In this program you are asked to take either calcium and vitamin D pills or inactive pills (placebos). Only women in the Dietary or Hormone programs may join this program.

- **Observational or Health Tracking**—If you are not able to join the other programs, your medical history and health habits will be followed in this program.

How do I decide which part of the study to join?

Staff at your Clinical Center will help you decide which program to join based on your medical history and general health habits, physical exam, and blood tests. All parts of the study are equally important, so don't feel disappointed if you aren't able to join certain programs.

If you join the Dietary, Hormone Replacement, or Calcium and Vitamin D Programs, you will be placed by chance into a study group. This process, called "randomization," is like flipping a coin. It is not influenced by any special factors, and neither you or the center staff can choose which study group you are placed in.

How long does the study last?

You will be in the study for a total of 8-12 years, depending on what year you enter the study. This is necessary to obtain the information we need and to study the long-term effects of the different programs.

What does being in the study involve?

This will depend on which program you join and which study group you are placed in. For example, women in the Hormone Replacement Program will take a study pill on a daily basis, while women in the Dietary Program may be asked to attend regular dietary sessions. Women in all parts of the study will be asked to come to their Clinical Center for follow-up visits.

The health of women in the study will be followed by specially trained staff at the Clinical Centers. Certain routine tests will be provided, although these are not meant

to replace your usual health care. Depending on which programs you join, you may receive study pills and dietary sessions. You will not have to pay for any study visits, study tests, or pills.

You don't need approval from your doctor to sign up for the study. However, it will be important for your doctor to know about any pills or dietary advice you might be getting in the study.

During the study, you should continue to see your regular doctor or healthcare provider just as you always have. Any pill, dietary advice, or test you might receive in the study should not replace your regular medical care.

Again, thank you for your interest in the Women's Health Initiative! Being a part of this important project may help you learn more about your own health, and will provide information that may eventually improve the health of women for generations to come!

Promoting health for future generations!

Figure F2.2.
Welcome to the Dietary Change Group of the WHI!

Welcome to the Dietary Change Group of the WHI Dietary Program!

The Women's Health Initiative (WHI) is one of the first major research studies of women and their health. About 48,000 women from centers across the United States are taking part in the Dietary Program of the WHI. The Dietary Program was designed to help us study the effect of a low-fat diet on a women's risk for breast cancer, colon cancer, and heart disease. The purpose of the Dietary Program is to give us clear answers about whether following an eating plan that is low in fat and high in fruits, vegetables, and grains affects a woman's health and whether it can help prevent disease.



What will I be doing?

You have been assigned to the Dietary Change Group, also called the Intervention Group. As part of this group, you will be asked to make important changes in your eating, shopping, and meal preparation habits. You will be asked to reduce the amount of high-fat foods you eat and to eat more fruits, vegetables and grains. All of these changes will take time, and we don't expect you to do everything by yourself.

Group Sessions:

To help you make changes in your eating, we have planned a series of group sessions that will give you a chance to learn new information and share experiences with other women who are also changing their eating patterns. Each group will be made up of 8-15 women like you. We encourage you to take an active part in your group. During these sessions, your nutritionist will give you information about how you can involve your family and friends in these changes, if they are interested.

During the first year there are a total of 18 group sessions and one individual counseling session. Each session will last about 2 hours. The first six sessions will be held once a week. The next three sessions will be held every other week. For the remainder of the first year, groups will meet once a month.

After the first year, group sessions will be held once every three months. These sessions will help you maintain the changes you make during the first year.

Follow-up Visits:

Women in the Dietary Change Group will also be asked to come to their Clinical Center for follow-up visits at least once and perhaps twice a year. These visits are very similar to your screening visits. During each visit, you will be asked questions about your health and you may have some blood tests. Every two years you will be asked to have a mammogram also. (If you are also enrolled in the Hormone Program, you will be asked to have a mammogram every year.) We will call and remind you about these visits. We'll also send you a copy of our health newsletter once a year. If you have any questions about these visits or about the study, please feel free to call the staff at your Clinical Center.

Review:

As a member of the Dietary Change Group you are asked to:

- Make changes in your eating habits
- Attend group sessions:
 - Once a week for 6 weeks (6 sessions)
 - Once every two weeks for the next 6 weeks (3 sessions)

- Once a month for 9 months (9 sessions)
- 4 times per year until the study ends

- Attend a make-up session for any group session you miss
- Attend one individual counseling session
- Come to the clinic every once or twice a year for health checks

How did I get into the Dietary Change Group?

Women in the Dietary Program are placed by chance into one of two groups by a process called "randomization." This process is like flipping a coin. It is not influenced by any special factors. The computer spins the numbers and one person is chosen for one group while another is chosen for the other group. Women are assigned to one of two groups:

- 1) **A Dietary Change**, where women learn ways to change their eating patterns.

OR

- 2) **A Comparison Group**, where women are expected to eat as they usually do.

Women in both groups are important to the study. Since women in the Comparison Group do not get help to change what they eat, you may want to know why this group is important to the study. The purpose of studies like the WHI is to find answers to health questions. These answers are useful only if strict rules of scientific research are followed. One of these important rules is to have two groups: one that changes and one that does not. In the Dietary Program, one group changes what they eat (the Dietary Change Group) and one group does not (the Comparison Group). The study will compare the health of women in the two groups. Women in both groups are important to the study. With your help, the study may find answers that can lead to better health.

The Dietary Program is an important part of the Women's Health Initiative. Take pride in your role as a member of the Dietary Change Group. Being a part of this project may help you learn more about your own health, and will provide information that may eventually improve the health of women for generations to come!

Again, thanks for your interest in the Dietary Program!

Figure F2.3.
Welcome to the Comparison Group of the WHI Dietary Program!

Welcome to the Comparison Group of the WHI Dietary Program!

The Women's Health Initiative (WHI) is one of the first major research studies of women and their health. About 48,000 women from centers across the United States are taking part in the Dietary Program of the WHI. The Dietary Program was designed to help us study the effect of a low-fat diet on a women's risk for breast cancer, colon cancer, and heart disease. The purpose of the Dietary Program is to give us clear answers about whether following an eating plan that is low in fat and high in fruits, vegetables, and grains affects a woman's health, and whether it can help prevent disease.



What will I be doing?

You have been assigned to the **Comparison Group** of the Dietary Program. As a member of this group, you are expected to continue to eat as you normally do. You are not asked to change your eating patterns or attend any dietary sessions. You may be asked to keep track of the foods you eat by keeping a food record for a few days every year.

Follow-up Visits:

Women in the Comparison Group will be asked to come to their Clinical Center for follow-up visits at least once and perhaps twice a year. These visits are very similar to your screening visits. During each visit, you will be asked questions about your health and you may have some blood tests. Every two years you will also be asked to have a mammogram. (If you are also enrolled in the Hormone Program, you will be asked to have a mammogram every year.) We will call and remind you about these visits.

We'll also send you a copy of our health newsletter once a year. If you have any questions about these visits or about the study, please feel free to call the staff at your Clinical Center.

How did I get into the Comparison Group?

Women in the Dietary Program are placed by chance into one of two groups by a process called "randomization." This process is like flipping a coin. It is not influenced by any special factors. The computer spins the numbers and one person is chosen for one group, while another is chosen for the other group. Women are selected into one of two groups:

1) **A Comparison Group**, where women are expected to eat as they normally do.

OR

2) **A Dietary Change Group**, where women learn to change their eating patterns.

The women in the Comparison Group are just as important as those in the Dietary Change Group. The purpose of studies like the WHI is to find answers to health questions. These answers are useful only if strict rules of scientific research are followed. One of these important rules is to have two groups: one that changes and one that does not. In the Dietary Program, one group

changes what they eat (the Dietary Change Group) and one group does not (the Comparison Group).

The study will compare the health of the two groups. Women in both groups are important to the study. With your help, the study may find answers that can lead to better health.

The Dietary Program is an important part of the Women's Health Initiative. Being a part of this project may help you learn more about your own health, and will provide information that may eventually improve the health of women for generations to come!

Again, thanks for your interest in the Dietary Program!

Figure F2.4.
Welcome to the Hormone Replacement Program of the WHI!

Welcome to the Hormone Replacement Program of the Women's Health Initiative!

The Women's Health Initiative (WHI) is one of the first major research studies of women and their health. Over 27,500 women from centers across the United States are taking part in the Hormone Replacement Program of the WHI. This program was designed to help us study the effect of hormone replacement on a woman's risk for heart disease and bone fractures. As women go through menopause ("change of life"), their bodies make smaller amounts of female hormones. Past studies have suggested that taking female hormone pills may decrease the chances of getting heart disease or fractures. However, it is not clear from these studies whether women who take female hormones may already be healthier than those who don't, or whether the hormones themselves protect against heart disease or fractures. The WHI is specially set up to find out if female hormone pills improve women's health by protecting against these diseases.



What will I be doing?

Women in the Hormone Replacement Program are asked to:

- Take one study pill containing either hormone medicines or an inactive medicine ("placebo") each day
- Keep an "HRT calendar" (if you haven't had a hysterectomy) of any menstrual

bleeding you might have while taking the study pills

- Visit the Clinical Center every 6 months for follow-up interviews and more study pills, *AND*
- Once a year for an exam similar to the one during the screening visits

Follow-up Visits

Women in the Hormone Replacement Program will also be asked to come to the Clinical Center every 6 months for follow-up visits. These visits are similar to your screening visits. During each visit, you will be asked questions about your health. Around the time of each yearly visit, you will be asked to have a mammogram. You may also have blood tests or other exams on some of the yearly visits. We will call and remind you about these visits. We'll also send you a copy of our health newsletter once a year. If you have any questions about these visits or about the study, please feel free to call the staff at your Clinical Center.

Which hormones will I be taking?

If you have not had your uterus removed, you are placed by chance into 1 of 2 groups:

- 1) A group given pills with a combination of estrogen + progesterone hormones, **OR**
- 2) A group given inactive pills with no hormones in them at all (placebos)

If you have had your uterus removed, you are placed by chance into 1 of 2 groups:

- 1) A group given pills with estrogen alone, **OR**
- 2) A group given inactive pills (placebos)

Because this is a research study, neither you nor the staff at your Clinical Center will know exactly which group you are in. Your placement into these groups is done by chance by a computer. Neither you nor the WHI staff will know whether your study pills are hormone medicines or inactive pills.

Do these hormones have side effects?

Any medicine or pill can have possible benefits and risks. Side

effects are physical or emotional changes that might happen when taking any medication. An example of a side effect is shakiness or nervousness after drinking too much coffee.

Your consent form and HRT Symptoms Brochure describe changes that could occur with these hormones. Remember, some side effects (for example, headaches, bloating, irritability) often occur for many reasons other than taking hormones. Of course, many women will not have any changes at all, and some may feel even better than before.

The Hormone Replacement Program is an important part of the WHI. Being a part of this project may help you learn more about your own health and will provide information that may eventually improve the health of women for generations to come!

Why are women placed in different groups?

The purpose of studies like the WHI is to find answers to health questions. These answers are useful only if strict rules of scientific research are followed. One rule

is to have at least 2 groups: 1 or more groups that change (the intervention groups), and 1 group that does not change (the comparison group). In this study, the intervention groups are made up of the women who take the pills containing hormones, and the comparison group is made up of the women who take the inactive pills (placebos). The study will compare the health of women in each of the groups.

A second rule that must be followed is that women are assigned to 1 group or another by a process called "randomization." This process is like flipping a coin. It is not influenced by any special factors. A computer spins the numbers and places each woman into either one of the intervention groups or the comparison group. It's totally by chance, so no one knows beforehand who will be in which group. Remember, women in all groups are equally important to the study.

***Again, thanks for your interest in
the Hormone Replacement Program!***

Figure F.2.5
CaD Information Sheet

Replaced by CaD Handbook
(Appendix F, Figure 3.15 (1/03))

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Figure F2.6.
Welcome to the Observational Study of the WHI!
(Non-Bone Density Sites)

Welcome to the Observational Study of the Women's Health Initiative!

The Women's Health Initiative (WHI) is one of the first major studies of women and their health. Being a part of this important project will help us learn more about women's health, and will help doctors develop better ways to prevent disease. About 100,000 women aged 50-79 from centers across the United States will take part in the Observational Study. Before now, few studies have focused on the special health concerns of women. This is the first study to examine the health of a very large number of women over a long period of time.



What is the Observational Study?

There are two parts to the Women's Health Initiative:

- ***The Clinical Trial***—In this part, we will study how changes in diet, hormone pills, and calcium and vitamin D pills might affect the major causes of death and poor health in women: cancer, heart disease, and bone fractures.
- ***The Observational Study***—In this part, the health of thousands of women will be followed for several years, so that we can learn more about women's health in general and about the causes of disease in women. Women in the Observational Study are not asked to change their diets or take any study pills.

Because you were not able or willing to join the WHI Clinical Trial, you have been asked to join the Observational Study, a very important

study to look at the relationship between lifestyle factors, health, and quality of life. We will gather information on health habits (for example, your physical activity and diet), physical measurements (such as blood pressure and body weight), and blood tests to see how these factors affect health and quality of life.

What will I be doing?

After the first clinic visit and completion of questionnaires, your lifestyle and health habits will be followed for about 8-12 years. During this follow-up period, you will be contacted by mail each year and asked to complete health update questionnaires and mail them back to the clinic. These questionnaires will take a lot less time to complete than the questionnaires at the

beginning of the study. You will also receive a WHI newsletter each year, informing you of news about the study and general information about health in women your age.

You will return to the clinic in 3 years for a follow-up visit. Before the visit, you will be mailed questionnaires to complete and bring with you to the clinic visit. During the visit, we will review the questionnaires, and you will have many of the same physical tests and measurements you had as part of the first clinic visits.

Why is my participation important?

The Observational Study is an important part of the Women's Health Initiative.

By taking part in this study, you will help to increase scientific knowledge about ways to prevent breast cancer, colon and rectum cancer, heart disease, and fractures (broken bones) in women, and about the experiences and lifestyles that affect women's health as they get older.

Your participation is important to us. We need to follow the health of all women who join the Observational Study, so that our results will be accurate and scientific.

Being a part of this project may help you learn more about your own health, and will provide information that may eventually improve the health of women for generations to come!

***Again, thanks for joining the
Observational Study!***

Figure F.2.7
Welcome to the Observational Study of the WHI!
(Bone Density Sites)

Welcome to the Observational Study of the Women's Health Initiative!

The Women's Health Initiative (WHI) is one of the first major studies of women and their health. Being a part of this important project will help us learn more about women's health, and will help doctors develop better ways to prevent disease. About 100,000 women aged 50-79 from centers across the United States will take part in the Observational Study. Before now, few studies have focused on the special health concerns of women. This is the first study to examine the health of a very large number of women over a long period of time.



What is the Observational Study?

There are two parts to the Women's Health Initiative:

- ***The Clinical Trial***—In this part, we will study how changes in diet, hormone pills, and calcium and vitamin D pills might affect the major causes of death and poor health in women: cancer, heart disease, and bone fractures.
- ***The Observational Study***—In this part, the health of thousands of women will be followed for several years, so that we can learn more about women's health in general and about the causes of disease in women. Women in the Observational Study are not asked to change their diets or take any study pills.

Because you were not able or willing to join the WHI Clinical Trial, you have been asked to join the Observational Study, a very important study to look at the relation

between lifestyle factors, health, and quality of life. We will gather information on health habits (for example, your physical activity and diet), physical measurements (such as blood pressure, body weight, and bone density), and blood tests to see how these factors affect health and quality of life.

What will I be doing?

After the first clinic visit and completion of questionnaires, your lifestyle and health habits will be followed for about 8-12 years. During this follow-up period, you will be contacted by mail each year and asked to complete health update questionnaires and mail them back to the clinic. These questionnaires will take a lot less time to complete than the questionnaires at the beginning of the study. You will also receive a WHI newsletter each year, inform-

ing you of news about the study and general information about health in women your age.

You will return to the clinic every 3 years for a follow-up visit. During the visit, you will have some of the same physical tests and measurements you had as part of the first clinic visits, including a bone density scan.

Why is my participation important?

The Observational Study is an important part of the Women's Health Initiative. By taking part in this study, you will help to increase scientific knowledge about ways to prevent breast cancer, colon and rectum cancer, heart disease, and fractures (broken bones) in women, and about the experiences and lifestyles that affect women's health as they get

older.

Your participation is important to us. We need to follow the health of all women who join the Observational Study, so that our results will be accurate and scientific.

Being a part of this project may help you learn more about your own health, and will provide information that may eventually improve the health of women for generations to come!

***Again, thanks for joining the
Observational Study!***

F.3 Participant Handouts

HRT only

Figure F.3.1
About Calcium in Your Diet



About Calcium in Your Diet

A report from the National Academy of Sciences recommends that adults 51 years of age and older should have a calcium intake of 1200 mg every day.

One of the most common sources of calcium is milk. If you don't like to drink milk, you could use it in soups, puddings, or on cereals. You might also add dry milk powder to casseroles, soups, or stews to increase your calcium. Non-fat or low-fat options are available for most dairy foods. If you can't drink milk or are allergic to milk products, look at the table below for ideas.

Vitamin D is needed for your body to use the calcium well. Vitamin D fortified milk is the best food source of vitamin D. Your body can make vitamin D with the help of sunlight.

High (over 200 mg calcium)	Moderate (100-200 mg calcium)	Modest (under 100 mg calcium)
Instant breakfast packet, made with milk Evaporated milk, undiluted (1/2 cup) Flan or junket, made with milk Milk (or lactase-treated milk) Yogurt, plain or fruit-flavored Instant oatmeal, fortified Orange juice, calcium-fortified Frozen yogurt Sardines, in tomato sauce (3 oz.) Buttermilk Pudding or custard, made with milk Tofu, firm, calcium processed Dry milk powder (1/4 cup)	Mustard greens, cooked Turnip greens, cooked Ice milk Sherbet Salmon, canned with bones Okra, cooked Blackstrap molasses (1 TB) Bok choy, cooked Baked beans, canned Macaroni and cheese Cold cereal, calcium-fortified Cheese, most types (1 oz.) Black beans, cooked Tofu, regular Cottage cheese Refried beans, canned Rutabaga, cooked Calcium groupings are based on 1 cup serving size, unless otherwise noted on table.	Scallops, cooked (3 oz.) Broccoli, cooked English muffin (1 whole) Garbanzo beans, cooked Clams, or mussels, cooked (3 oz.) Ricotta cheese (1 ounce) Oysters, cooked (3 oz.) Artichoke, globe cooked Egg substitute (1/2 cup) Orange (1 medium) Kidney beans, cooked White bread (2 slices) Kale, cooked Oatmeal, quick cooking Cream soup, canned made with water Black-eyed peas, cooked

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Figure F.3.2
Hormone Program Handbook

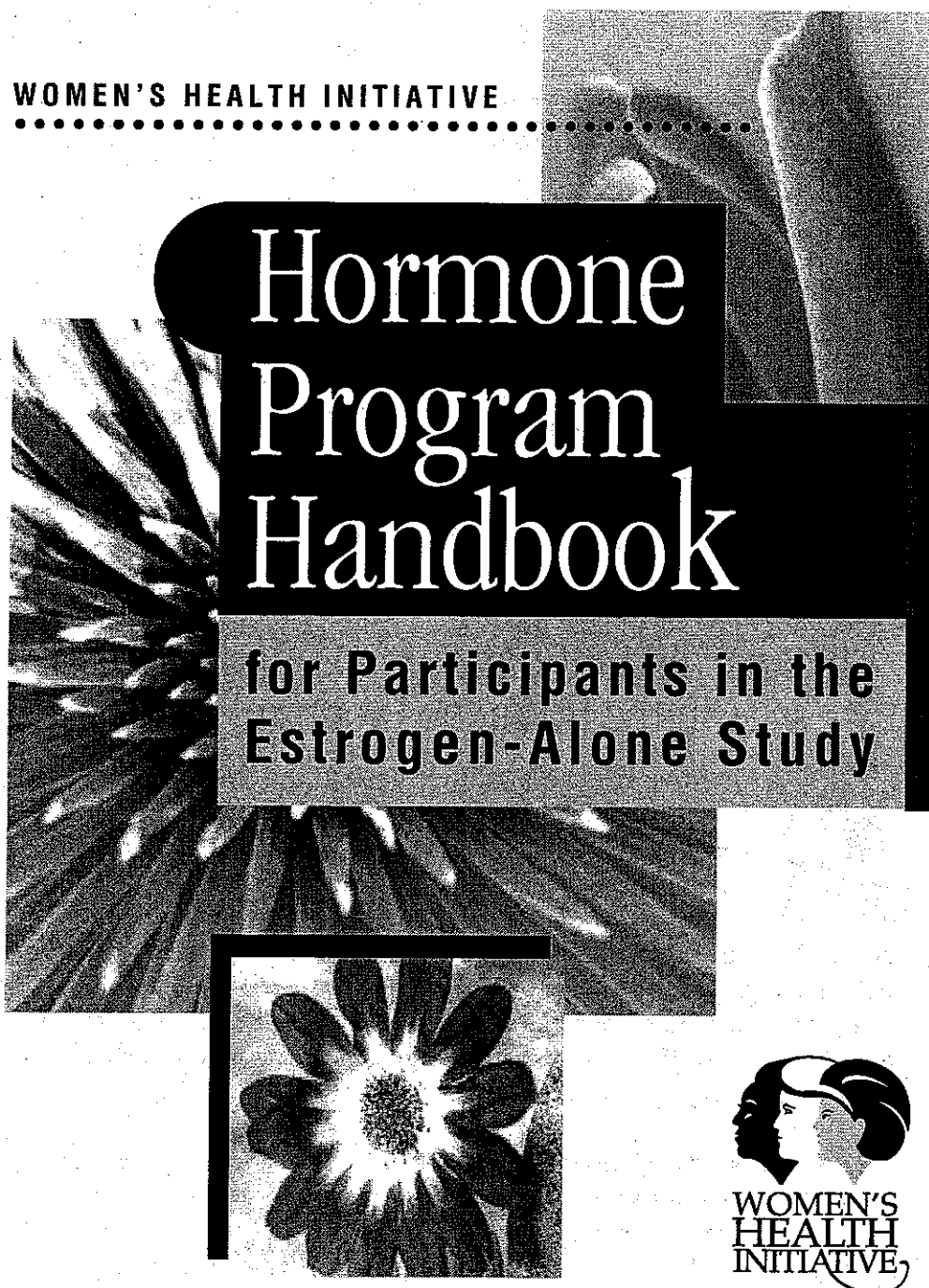


Figure F.3.2
Hormone Program Handbook, con't.

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Thank You for Continuing to Participate in the Hormone Program!



You have finished another year in the Women's Health Initiative Hormone Program! You should feel proud of being part of such a historic study—one that already changed our understanding about hormone therapy for postmenopausal women who have a uterus. Now we need to answer these important questions for women who have had a hysterectomy. Because of your participation, we are beginning to find answers for many important questions about women's health. The staff at your clinic, the WHI scientists, the medical community, and women of the world appreciate your dedication and commitment.

Because this study continues to be so important, please call your clinic before making any changes in hormone medications or your study pills. We can talk with you or your personal health care provider about ways to take care of your health while you remain on your study pills.

Figure F.3.2
Hormone Program Handbook, con't.

WOMEN'S HEALTH INITIATIVE



Is WHI Still Important?



You are in the WHI Estrogen-Alone study, in which women are continuing to take their WHI Hormone Program study pills. The balance of risks and benefits for women taking estrogen alone remains uncertain and is more important than ever to determine. In contrast, as you know from the 2002 WHI HRT Update, we asked women in the WHI Estrogen plus Progestin study to stop their study pills in July 2002, because it became clear that the risks of taking estrogen plus progestin exceeded the benefits after only 5 years. Even though these women are no longer taking study pills, they are still active participants in the WHI and continue to provide important health information. In particular, we now hope to learn how long the risks and benefits of estrogen combined with progestin persist after women stop taking these hormones. The WHI findings about estrogen plus progestin will help millions of women with a uterus, but health questions about estrogen alone still need answers.

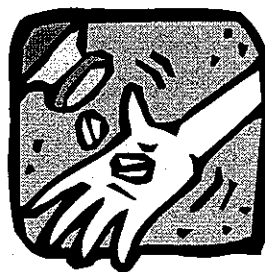


Figure F.3.2
Hormone Program Handbook, con't.

Women like you, who had a hysterectomy before they joined the Hormone Program, are true VIPs (Very Important Participants). You are helping us to get the answers that millions of other women and their physicians are waiting for!

In the past, most hormone studies did not randomly assign women to take active or placebo pills. Instead, they studied women who were already taking hormones and women who were not. We do not know if the results of these past studies were due to the hormones or because healthier women chose to take them. These earlier studies also did not last long enough or

have enough participants to give clear answers to key questions about long-term hormone use.

The WHI Estrogen-Alone study was designed to provide clear answers to questions about hormones and women's health. Thousands of women like you were "randomized" by a computer to take an active study pill or an inactive placebo pill over a long time. Neither you nor your WHI clinic staff knows whether you were assigned to take the active or placebo study pills. In this way, WHI will continue to find answers that scientists, physicians, and all women can trust.

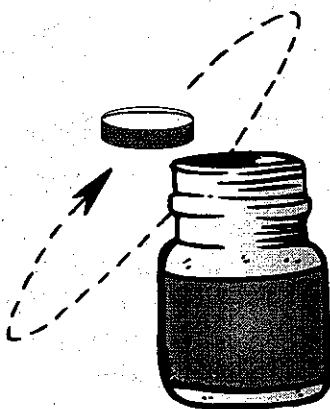
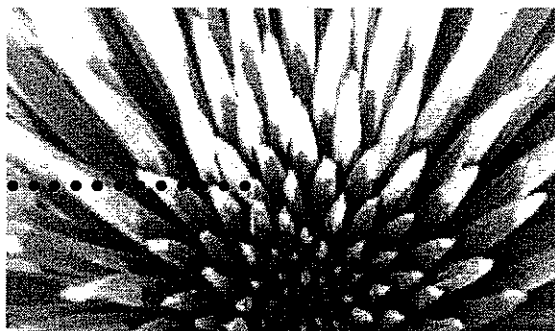


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WOMEN'S HEALTH INITIATIVE



What Should I Be Doing in the Hormone Program?



It is very important to women of today, as well as future generations of women, that you continue to be active in WHI. What we ask of you in the Hormone Program is the same as what we have asked in the past:

- ✓ **Take a study pill every day**
- ✓ **Have a mammogram every year**
- ✓ **Call your clinic before making any changes in hormone medications or your study pills**
- ✓ **Provide health information every 6 months when we contact you**
- ✓ **Visit your clinic at least once a year**
- ✓ **Let your personal health care provider know that you are in the WHI Estrogen-Alone study**

Take a study pill every day.

WHI is a very long study. You may feel differently now about taking your study pills every day compared to when you first joined. We hope that the recent response to the WHI study findings has helped you understand how important your participation—and taking your study pills every day—is to women like you throughout the world.

If you are having problems taking or remembering to take your study pills, please call your WHI clinic. The clinic practitioner can work with you on ways to remember to

Figure F.3.2
Hormone Program Handbook, con't.

take your study pill every day. Your family or friends may also help remind you to take your study pills.

Here are some pill-taking hints that you can try on your own:

- Take your study pill at the same time every day. The time you choose is not important, but having a routine that you always follow might help.
- Keep your study pills next to something you use every day—your toothbrush, bedside table, kitchen table, or other medications.
- Keep your pills in a WHI weekly pill organizer (we can provide one). You can tell by looking at your organizer whether or not you have taken that day's study pill.
- If you take a trip, be sure to pack your study pills.
- If you forget to take your study pill at your regular time, try to take it that day, when you remember. If you wake up in the morning and realize you did not take a pill at all the day before, just take your regular pill for that day—do not try to “catch up”.

- If you get sick and cannot keep food down, do not try to take your study pills. If this persists, call your personal health care provider and wait to take your study pills when you can have food and drink without vomiting (throwing up). Let your WHI clinic practitioner know about the days you could not keep food down or take your pills.

- **Remember to bring your study pill bottles back at your next clinic visit.**

- Remind yourself of the reasons you joined the WHI in the beginning. Tape an article about the historic WHI findings onto your refrigerator and feel proud about your participation in such an important study.

Even if your schedule for taking pills changes at some point, you may be able to move back to a daily pill schedule later. The more that women take their pills in the same way, the more reliable our answers about hormones and women's health will be.

Have a mammogram every year.

You should have a mammogram every year before you come into

Figure F.3.2
Hormone Program Handbook, con't.

the WHI clinic for your clinic visit (unless the clinic does the mammogram during your visit).

We look at the mammogram report for your safety, before we give you more study pills. In fact, we may not be able to continue to give you study pills until a mammogram report is received.

Call your clinic before making any changes in hormone medications or your study pills.

Your personal health care provider may suggest that you start prescription hormone therapy or stop your study pills. Your WHI clinic practitioner will work with you and your provider to discuss how to continue your study pills and take care of your health care needs and concerns.

Provide health information every 6 months when we contact you.

We will contact you every 6 months by telephone or at your annual clinic visit to ask questions about your health. Some of these questions are asked to ensure that it is safe for you to continue in the Estrogen-Alone study. Other

questions are about symptoms, like breast changes, that you might have experienced. We will review your medical history and ask about any changes to your health since your last contact or visit.

Visit your clinic at least once a year.

Every year, near the anniversary of the date you joined the Hormone Program, we ask you to return to the clinic. You will fill out questionnaires each time. We will take your blood pressure and several other measurements. The clinic practitioner will do a breast exam and possibly a Pap smear (if you have a cervix). During your annual visit, please feel free to ask your WHI clinic practitioner about any concerns you may have about being in the Hormone Program.

Let your personal health care provider know that you are in the WHI Estrogen-Alone study.

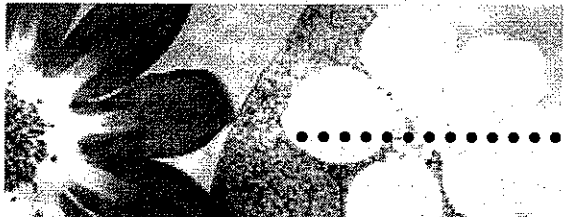
We can give you medical chart labels or other information for your provider about the WHI and the Estrogen-Alone study.

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Please remember to bring your study pill bottles and pill organizers to your clinic visits. We need to collect all study pill bottles and any remaining study pills at your routine visits.

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Figure F.3.2
Hormone Program Handbook, con't.



WOMEN'S HEALTH INITIATIVE

Possible Hormone-Related Side Effects



either you nor the WHI staff knows if you are taking active or inactive study pills. However, you may have noticed some symptoms or changes while you have been taking these pills (which may or may not be caused by the pills):

- **Breast Tenderness**

You may have noticed some soreness or swelling in your breasts. Although not necessarily related to hormones, if this is a problem for you, try using less caffeine and salt. Coffee, tea, soda, and chocolate all have caffeine in them. Drinking more water may also help decrease breast tenderness. Check the fit and support of your bras. Sleeping in a bra that fits well can also help decrease breast tenderness.

- **Vaginal Bleeding or Spotting**

Because you have had your uterus removed, you should not

experience any vaginal bleeding. If you do notice any vaginal bleeding or spotting, please report it right away to your WHI clinic practitioner.

- **Vaginal Discharge**

You might have noticed some slight vaginal discharge since starting study pills; this is normal. Please contact your personal health care provider, however, if you have a burning feeling or pain when you go to the bathroom, or if you have vaginal itching, or if the discharge is green or bloody. These changes are not normal.

Figure F.3.2
Hormone Program Handbook, con't.

WOMEN'S HEALTH INITIATIVE



Hormone-Related Risks



You are in the Estrogen-Alone study. Taking estrogen alone is not the same as taking estrogen plus progestin. We reported on the health risks of taking estrogen plus progestin in the July 17, 2002 *Journal of the American Medical Association*. The balance of risks and benefits for women taking estrogen alone is still uncertain. The WHI Data Safety and Monitoring Board (DSMB) has recommended that the Estrogen-Alone study continue. The DSMB will continue to evaluate the study results every six months and we will let you know about any changes that might affect your participation. However, as we told you when you joined the study, there are some possible risks related to taking pills that contain estrogen.

Risks related to taking hormones include:

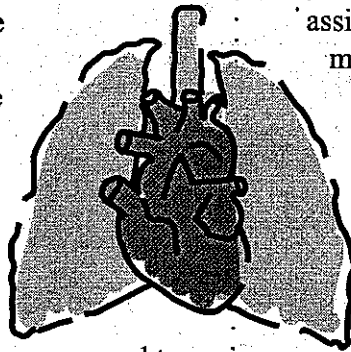
- Blood clots in your legs or lungs** (deep vein thrombosis or pulmonary embolism): Hormones can sometimes cause these types of blood clots, although the likelihood of having blood clots is low. Data from WHI suggests that for every 10,000 women taking estrogen plus progestin each year, 18 more women might develop blood clots compared

to women who are taking inactive (placebo) pills. We have a handout that shows exercises that help prevent deep vein thrombosis or pulmonary embolus. Please let us know if you have not received the handout, "*What You Should Know about Deep Vein Thrombosis (DVT)*," or if you would like another copy.

Figure F.3.2
Hormone Program Handbook, con't.

► **Heart attacks or strokes:**

Information from the WHI Hormone Program indicates that there was a small increase in the number of heart attacks and strokes in women taking active hormones compared to placebo pills. In the Estrogen plus Progestin study, for every 10,000 women assigned to active estrogen and progestin study pills each year, 7 more women had a heart attack and 8 more women had a stroke compared to women assigned to placebo.



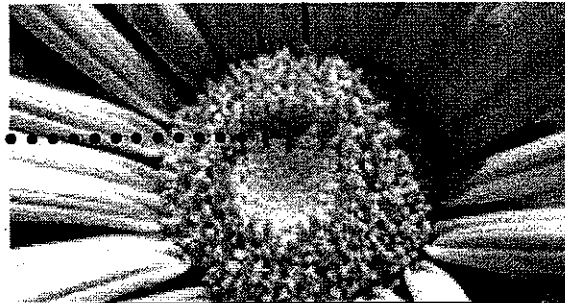
- **Breast cancer:** As we have informed you, there was no increased risk of breast cancer in women on active pills in the Estrogen-Alone study after 5 years. However, in the Estrogen plus Progestin study, for every 10,000 women assigned to active estrogen plus progestin each year, 8 more developed

invasive breast cancer by 5.2 years, compared to the women assigned to placebo. Furthermore, past research has suggested that women who take estrogen only for more than 10 years may also have an increased risk of breast cancer. The best way to screen for early signs of breast cancer is to have yearly mammograms and clinical breast exams. Early detection gives women their best chance for an early cure!

- **Gallbladder disease:** Estrogen has been associated with gallbladder problems, but these problems also occur in women who are not taking hormones. The most common symptom of gallbladder disease is pain in the right upper part of your abdomen (belly). Contact your personal health care provider if you have this type of pain.

Figure F.3.2
Hormone Program Handbook, con't.

WOMEN'S HEALTH INITIATIVE



Special Situations

When You Should Contact Your WHI Clinic

If you are thinking about starting any new hormones (estrogen, progestin, testosterone) or hormone-like medications known as SERMs (raloxifene, Evista®, or tamoxifen), please contact your WHI clinic practitioner before making any changes.

There are some special health situations that require stopping your study pills, at least temporarily. If you do need to stop, your WHI clinic practitioner will talk with you about the possibility of restarting your study pills.

If your health care provider says that you have any of the following new conditions, stop your study pills and call the WHI clinic:

- Heart attack or stroke:** A heart attack is sometimes called a "coronary" or a myocardial infarction, also referred to as an MI. A stroke is sometimes called a cerebrovascular accident or CVA. Stop your study pills if you have a heart attack or stroke. When you are feeling better, you can talk to your health care provider and WHI clinic practitioner about restarting.
- Transient Ischemic Attack (TIA):** Some people refer to a TIA as a "mini-stroke" because the symptoms of a TIA are very similar to those of a stroke. The difference is that the symptoms of a TIA usually go away within 24 hours and there is no permanent brain damage.

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Figure F.3.2
Hormone Program Handbook, con't.

However, many people who experience a TIA may have a stroke in the future. If your health care provider has told you that you had a TIA, you should stop your study pills. When you are recovered from your TIA you can talk to your provider and your WHI clinic practitioner about restarting your study pills.

- ▶ **Blood clots in your legs or lungs:** The medical term for a blood clot in the leg is a deep vein thrombosis (DVT) and for a blood clot in the lung is a pulmonary embolism (PE). If you have the less serious condition, "superficial phlebitis" (inflammation of the veins), you do not need to stop your study pills. Please talk with your health care provider if you are not sure which condition you have.

- ▶ **Breast cancer:** If you are diagnosed with any type of breast cancer, please stop your study pills and contact your clinic. For most other cancers, you can stay on study pills.

- ▶ **High triglycerides (over 1000 mg/dl):** Triglycerides are the fats in your blood. They are not the same as cholesterol, but may be tested during a regular fasting blood test. Having high triglycerides over 1000mg/dl is very rare but requires that you stop your study pills.

- ▶ **A major injury or surgery using general or spinal anesthesia:**

There may be a time when you have to be on strict bed rest or have anesthesia for surgery

(not local anesthesia). The decrease in activity when this

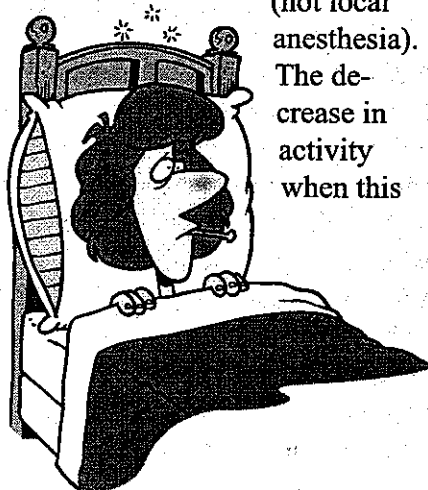


Figure F.3.2
Hormone Program Handbook, con't.

happens can put you at a higher risk for developing blood clots in your legs or lungs. Your health care provider may even want you to stop your study pills before the surgery. Please talk to your health care provider and the WHI clinic practitioner to find out if you should stop study pills ahead of time and when you can restart them after the surgery.

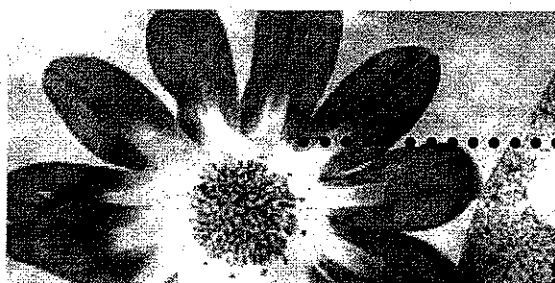
- **Malignant melanoma:** This is a rare form of skin cancer and is not the same as the more common skin cancers (like basal or squamous cell carcinoma). Please talk with your health care provider if you are not sure which type of skin cancer you have.

If any of the following other health situations occur, contact your WHI clinic practitioner to find out if you should stop your study pills:

- **Problems with your gallbladder:** The medical term for gall bladder problems is cholecystitis. Your health care provider makes this diagnosis based on specific symptoms and medical tests.
- **Problems with your pancreas:** The medical term for pancreatic problems is acute pancreatitis. Your health care provider makes this diagnosis based on specific symptoms and medical tests.

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Figure F.3.2
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WOMEN'S HEALTH INITIATIVE

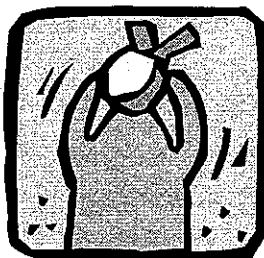
Other Health Changes in Postmenopausal Women



Some women have other kinds of symptoms after menopause. Past research studies have not shown these symptoms to be caused by hormones, but there are things that can help.

Headaches

Headaches are not generally related to the study pills, but if you have blurred vision, nausea, vomiting, weakness or tingling in any part of your body with a headache, call your personal health care provider immediately. Otherwise, try your usual headache treatment, if you have one. You might try resting in a dark room or taking an over-the-counter medication like acetaminophen (Tylenol®) or ibuprofen (Advil®, Motrin®).



Be sure you do not have any health problems that make it unsafe for you to take these medicines. If you are not sure you should take them, please call your personal health care provider for advice.

Weight Gain

Many women worry about weight gain. Most studies have found that women do not gain weight because of hormone therapy. As women get older, a small gain in weight is common.

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Figure F.3.2
Hormone Program Handbook, con't.

► ***Fluid retention, bloating, or change in bowel habits***

You may sometimes feel like you are bloated, swelling, or carrying extra water in your body. Try drinking more water and adding less salt when you are cooking or at the table. Choose foods with low "sodium" content.

Some women become constipated and have problems with their bowel movements. If you have bowel problems, try increasing the amount of fluids you drink—the more water you drink, the more liquid is available to soften your stool. You could also try increasing the amount of roughage you eat, like fresh (not cooked) fruits and vegetables, prunes, and prune juice. Be sure to drink plenty of fluids with these foods. If you are still having problems, you can try an over-the-counter mild stool softener (available in drug stores) for a few days. Increasing your activity or exercising more also helps with constipation.

► ***Irritability, anxiety, or depression***

There might be days when you do not feel quite like yourself. For almost no reason, you may feel sad, angry, or worried. Women experience these kinds of changes whether or not they are taking hormones. Your mood might get better if you make sure you eat right each day, get a good night's sleep, and take a break from your routine for an hour. Try decreasing your intake of caffeine (coffee, tea, caffeinated soft drinks, or chocolate) or alcohol. You might try starting a mild exercise program, like walking or stretching. Take more time for social activities. If you ever feel that you are so unhappy or depressed that you would think about hurting yourself, call your personal health care provider right away.

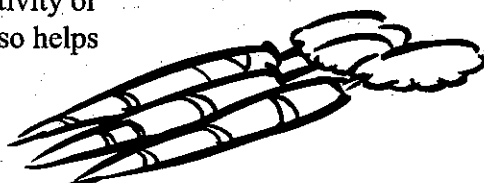
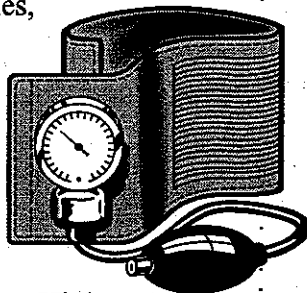


Figure F.3.2
Hormone Program Handbook, con't.

► **High blood pressure**

In past studies, on average, hormones have not been shown to increase or decrease blood pressure. High blood pressure is a common problem in older women. Usually there are no symptoms when you have high blood pressure. The only way to know if you have this problem is to have your blood pressure taken every 6 months at a health care office or pharmacy. Even if you are already on high blood pressure medications, these check-ups are important. High blood pressure is a risk factor for stroke and heart disease.



Try these tips if you have trouble sleeping:

- ◆ Decrease your caffeine (coffee, tea, soda, chocolate) and alcohol intake, especially in the hours before going to bed.
- ◆ Try doing some mild exercise earlier in the day.
- ◆ Plan a relaxing bedtime routine, like taking a warm bath.
- ◆ Stay away from heavy meals in the late evening.
- ◆ Avoid such things as watching television or doing paperwork in bed.

If you find that your sleeping problems do not go away, call your personal health care provider.

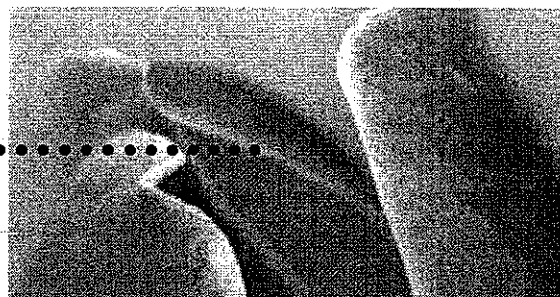
► **Sleeping problems**

At times, you might have trouble sleeping. Worry, frustration, or depression can sometimes keep you from getting a good night's sleep.



Figure F.3.2
Hormone Program Handbook, con't.

WOMEN'S HEALTH INITIATIVE



Frequently Asked Questions

“What can you tell me about the new kinds of estrogen-like medications called SERMs (Selective Estrogen Receptor Modulators)?”

SERMs (raloxifene, Evista®, tamoxifen, or Nolvadex®) act like estrogen in some parts of the body but opposite from estrogen in other parts. Some recent news stories have said that SERMs can be used as alternatives to hormones. SERMs may strengthen bones and reduce bone fractures and may reduce the risk of breast cancer. However, there is no convincing evidence that SERMs protect the heart or the brain. Like hormones, these medications also increase the risk of blood clots. We can give

you a WHI handout, “*What You Should Know About SERMs*”, if you would like more information about these new medications. If you are thinking about starting SERMs, please call your WHI clinic practitioner to discuss this before you do so.

“My doctor said I am at high risk for osteoporosis or brittle bones. Should I be taking special medications?”

Your personal health care provider is the best person to decide what you should be doing to treat or prevent osteoporosis (bone thinning). We can give you a WHI handout, “*What You Should Know About Osteoporosis*,” if you would like more information about this condition. If your personal health care provider wants you to take

Figure F.3.2
Hormone Program Handbook, con't.

hormones to treat or prevent this condition, please contact us first. We can talk with your provider about other treatments available so that you do not have to stop study pills.

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"How do I evaluate new medical news?"

Because the issue of the health effects of hormone therapy is so important, many scientists are studying this issue in many ways. Studies on hormones and women's health are often published in scientific journals and presented at scientific meetings. Many of these studies are reported in the press because the topic attracts national attention. The quality of these new studies varies a great deal, and they are not always relevant to the WHI Hormone Program. Studies that analyze health outcomes of menopausal hormones used in the past or from small local populations may be difficult to interpret. For example, studies that observe women who have chosen (with their own doctors) to take hormones may report different results from the randomized clinical trial in which you are participating. Sometimes studies

appear in the media that only confirm things we already know and get more publicity than they should.

Any new studies could be important, and we recognize that you may be interested in them as they appear. WHI investigators review new studies on hormones from around the world. Should a study appear that we determine has implications for your participation in WHI, we will notify you as soon as possible. If a study about menopausal hormones comes to your attention and you would like to know more about it, please contact your WHI clinic. One of our investigators would be happy to provide more information.

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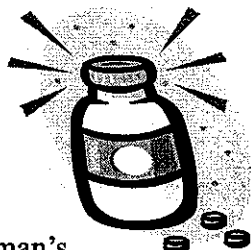
"I heard about a study that reported a higher risk of ovarian cancer in women taking estrogen alone. Given this news, should I still take my Estrogen-Alone study pills?"

An observational study published in 2001 and another published in July 2002 reported a higher risk of ovarian cancer in women who took estrogen only for 10 or more years. The WHI DSMB reviewed this study along with WHI data and

Figure F.3.2
Hormone Program Handbook, con't.

recommended
that we
continue the
WHI Estrogen-
Alone study.

Generally, a woman's
risk of ovarian cancer is
small compared to her risk of the
other diseases being studied in the
WHI—breast cancer, colorectal
cancer, heart disease, or hip
fractures.



***“Why aren't you using natural
plant hormones?”***

Millions of postmenopausal
women have been using the
estrogen we are testing in WHI for
decades. Most of the research that
suggested estrogen may benefit the
heart was based on this type of
estrogen (conjugated equine
estrogens). That is why it was
chosen for WHI. Much less is
known about the benefits and risks
of other types of hormones, like
natural plant hormones.

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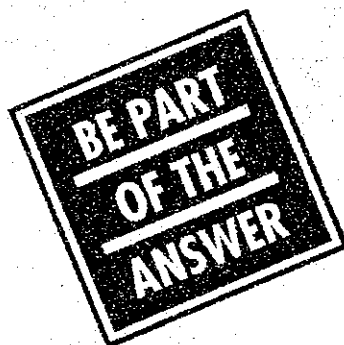
You Are Important to WHI!

Only through your continued participation will WHI be able to answer the
many questions about hormones and women's health. It is important that
you continue to take your study pills **EVERY DAY** and come to all your
clinic visits. Without you, there can be no Hormone Program or WHI!

**If your personal health care provider asks you to stop your study
pills, please call us (or have your provider call us). We
understand that your health care needs might change. We would
like to work with you and your provider to see if there is a way to
safely keep you on study pills and get the care your personal
health care provider recommends.**

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Figure F.3.2
Hormone Program Handbook, con't.



**Thank you for your continued participation
in the Women's Health Initiative.
Future generations of women will be grateful
for your contribution to this
important research!**

Hormone Program Handbook, Ver. 6, 1/30/03

Figure F.3.3
Keeping Track of Goals

Women's Health Initiative -- Keeping Track of Goals

Name: _____ Fat Gram Goal: _____ Session # _____ Group # _____
 Fat Gram Score: _____ F/V Score: _____ Grain Score: _____

One Fruit/Vegetable Serving = 1/2 cup cut up fruit or vegetable • 1/2 cup potatoes • 1 medium piece of fruit
 1 cup raw leafy vegetable • 3/4 cup juice • 1/4 cup dried fruit

One Grain Serving = 1 slice bread • 1/2 bagel • 1/2 cup cooked cereal or grits • 1 cup cold cereal
 8 crackers • 3 cups popcorn • 1/2 cup pasta, rice, or noodles • 1/2 cup cooked dried peas or beans

Date: _____ F/V Serv: □□□□□□□□ = ____ Grain Serv: □□□□□□□□ = ____ Fat Grams: Breakfast = _____ Lunch = _____ Dinner = _____ Snacks = _____ Total Fat Grams = _____	Date: _____ F/V Serv: □□□□□□□□ = ____ Grain Serv: □□□□□□□□ = ____ Fat Grams: Breakfast = _____ Lunch = _____ Dinner = _____ Snacks = _____ Total Fat Grams = _____	Goals / Notes.....
Date: _____ F/V Serv: □□□□□□□□ = ____ Grain Serv: □□□□□□□□ = ____ Fat Grams: Breakfast = _____ Lunch = _____ Dinner = _____ Snacks = _____ Total Fat Grams = _____	Date: _____ F/V Serv: □□□□□□□□ = ____ Grain Serv: □□□□□□□□ = ____ Fat Grams: Breakfast = _____ Lunch = _____ Dinner = _____ Snacks = _____ Total Fat Grams = _____	Goals / Notes.....
Date: _____ F/V Serv: □□□□□□□□ = ____ Grain Serv: □□□□□□□□ = ____ Fat Grams: Breakfast = _____ Lunch = _____ Dinner = _____ Snacks = _____ Total Fat Grams = _____	Date: _____ F/V Serv: □□□□□□□□ = ____ Grain Serv: □□□□□□□□ = ____ Fat Grams: Breakfast = _____ Lunch = _____ Dinner = _____ Snacks = _____ Total Fat Grams = _____	Goals / Notes.....

Keeping Track of Goals Instruction Sheet

Use **KEEPING TRACK OF GOALS** to monitor your progress. Record Fruits/Vegetables, Grains and/or Fat Grams. Plan your meals, budget for special occasions, or set new goals for yourself.

Boxes on Left:

1. Check a box for each Grain and/or Fruit/Vegetable Serving you eat. Total the number of servings.
See serving guide at top of page.
2. Record Fat Grams for meals and snacks.
3. Total Fat Grams for the day.
4. Average your totals and record scores at the top of the page.

Box on Right:

Use Goals/Notes for any of the following:

- Note high risk situations
- Plan your meals/snacks
- Record your positive self talk message or your goals
- Budget your fat grams

*****Example*****

Women's Health Initiative -- Keeping Track of Goals

Name: Emily Fat Gram Goal: 25 Session # 2 Fall Group # 106
Fat Gram Score: 20 F/V Score: 5 Grain Score: 6

One Fruit/Vegetable Serving = 1/2 cup cut up fruit or vegetable • 1/2 cup potatoes • 1 medium piece of fruit

1 cup raw leafy vegetable • 3/4 cup juice • 1/4 cup dried fruit

One Grain Serving = 1 slice bread • 1/2 bagel • 1/2 cup cooked cereal or grits • 1 cup cold cereal

8 crackers • 3 cups popcorn • 1/2 cup pasta, rice, or noodles • 1/2 cup cooked dried peas or beans

Date: <u>October</u> <u>15</u> F/V Serv: ■■■■■□□ = <u>5</u> Grains Serv: ■■■■■□□ = <u>6</u> Fat Grams: Breakfast = <u>4</u> Lunch = <u>5</u> Dinner = <u>9</u> Snacks = <u>2</u> Total Fat Grams = <u>20</u>	Date: <u>October</u> <u>16</u> F/V Serv: ■■■■■□□ = <u>6</u> Grains Serv: ■■■■■□□ = <u>6</u> Fat Grams: Breakfast = <u>3</u> Lunch = <u>4</u> Dinner = <u>10</u> Snacks = <u>2</u> Total Fat Grams = <u>19</u>	Goals / Notes.... Plan for daughter's birthday party ... Budget 5 grams for two days. Fat gram goal for the day = 20.
---	--	--

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Figure F.3.4
Eating Pattern Changes

EATING PATTERN CHANGES

Name: _____ Group #: _____ From: _____ To: _____

- | | |
|---|--|
| <p>1. I used low-fat or fat-free products for snacks, sweets or desserts:
 NEVER SOMETIMES OFTEN
 pretzels low-fat crackers
 air-popped popcorn veggies
 modified baked goods fruits
 other: _____
 _____</p> | <p>6. I practiced assertiveness skills when eating out:
 NEVER SOMETIMES OFTEN
 helped to choose restaurant
 made special requests
 split an entree or dessert
 asked how dishes were prepared
 other: _____
 _____</p> |
| <p>2. I reduced my use of added fats:
 NEVER SOMETIMES OFTEN
 mayonnaise salad dressing
 margarine/butter peanut butter
 gravy sauces
 other: _____
 _____</p> | <p>7. I included more breads, cereals, grains and beans by using _____

 _____</p> |
| <p>3. I reduced the fat from meats:
 NEVER SOMETIMES OFTEN
 ate smaller portions removed skin
 ate leaner cuts used meatless meals
 trimmed all visible fat
 other: _____
 _____</p> | <p>8. I included more or new vegetables by _____

 _____</p> |
| <p>4. I changed my eating behaviors:
 NEVER SOMETIMES OFTEN
 modified recipes read labels
 made low-fat requests
 refused high-fat foods
 made low-fat choices readily available
 other: _____
 _____</p> | <p>9. I included more or new fruits by _____

 _____</p> |
| <p>5. I used low-fat or fat-free dairy products:
 NEVER SOMETIMES OFTEN
 milk cheese fresh yogurt
 frozen dairy desserts frozen yogurt
 other: _____
 _____</p> | <div style="border: 2px solid black; padding: 10px;"> <p>My goal during this time: _____

 _____</p> <p>Was I successful? Yes No</p> <p>If not, what would I do differently?

 _____</p> <p>Next goal: _____
 _____</p> </div> |

DIRECTIONS
for administering
the Eating Pattern Changes Form

Purpose: to provide information for a dialogue, or as a monitoring tool after a goal setting counseling session for optional or required extra help.

Population: participants who need extra assistance or who are not monitoring and may be retention challenges, or those who've missed sessions and refuse make-ups.

Nutritionist's responsibility:

1. Fill out top portion: Name, Group#, and dates you'd like the information to be gathered (one week, one month, etc.).
2. Discuss with participant "My goal during this time" and write it in.
3. Instruct participant to place this sheet in a prominent place in order to review the goal and monitor progress.
4. Instruct the participant to fill out the appropriate item on the sheet as they do it.
5. Repeat the sheet as necessary to get a clear picture of participant's behavior change.

Participant's responsibility:

1. Read each statement and circle the appropriate answer.
2. If you circle "often" or "sometimes", go on to circle the foods or behaviors that apply to you under that heading.
3. Evaluate success of goal set by you and your nutritionist.
4. Write in a new goal that you can discuss with your nutritionist.

Figure 3.5

What You Should Know About Deep Vein Thrombosis (DVT)[For women in HRT screening process]



WHI Update

September 1, 1997

WHAT YOU SHOULD KNOW ABOUT DEEP VEIN THROMBOSIS (DVT)

Thank you for participating in the Hormone Program of the Women's Health Initiative! You are helping us to get answers to questions about heart disease, cancer, and fractures. We have developed this fact sheet to give you some information about deep vein thrombosis or blood clots. A small number of women (and men, for that matter) can develop these types of blood clots in the veins of their legs or lungs. A few recently published studies have reported that hormone replacement therapy (HRT) may increase this risk a little, but the risk is still very low. We hope this information helps you to reduce your risk of developing deep vein thrombosis.

What is DVT?

Deep vein thrombosis or DVT is not common. It occurs when a blood clot forms in the large blood vessels of the legs (this is not the same as varicose veins). A small DVT usually does not cause problems. A large clot in the deep veins of the legs can cause problems because it can block blood flow. The most serious problem with DVT is that the clot can break loose, travel up to the lungs, and affect the lungs and heart. Usually, even a large clot will dissolve if treated early, and there will be little or no long-term health problems. Problems with DVT are far less common than heart attacks or strokes.

What causes blood clots?

Blood clotting is a normal reaction of the body. Blood clots often form because of an injury to your blood vessels (for example, a cut). Blood clots may also be caused by changes in your blood circulation. Blood circulation in your legs slows when you spend a long time in bed or are seated for many hours without moving, such as during a long plane flight or car trip.

Changes in blood clotting can also happen after a hip fracture or major operation; or when you have a severe illness, such as a heart attack, stroke, or some cancers. If you have had a blood clot in the past, you may have a higher risk of having one again. In a small number of people there is a family tendency to have more blood clots.

How will I know if I develop DVT?

Most of the time blood clots cause no problems. If the clot is small, you may not ever know you had it. Larger clots that form in the leg can cause swelling or pain of the affected leg. If both legs are swollen, it is probably not because of DVT, but you should see your doctor.

Rarely, a large clot in the leg can travel to the lung and cause a sudden shortness of breath or painful breathing. This condition is called a pulmonary embolism. Usually swelling and pain in the leg happens before shortness of breath and pain in the chest. Almost all the clots in lungs come from clots in the deep veins of the leg.

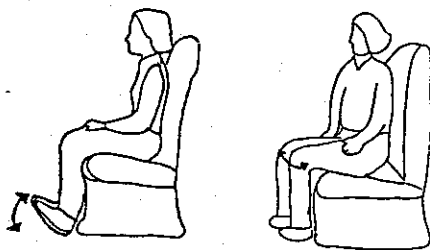
What is the role of hormones?

Studies published recently report that women taking hormone replacement therapy (HRT) can have an increased risk of blood clots in the legs or lungs. In some of these studies, the women were not as healthy as participants in the WHI or the HRT dosage was higher than the dosage used in our study. The actual risk of DVT was still much lower than that of other health problems like heart attacks or strokes.

The Women's Health Initiative will be looking carefully to see if hormones will increase blood clots in women. At this point, most women are not at risk of DVT. It is generally believed that the benefits of HRT are much greater than the risks.

How can I reduce my risk of blood clots?

Keep those legs moving! If you need to be in bed because of an illness, make sure you do leg and foot exercises several times each day (see exercises below). On a long plane flight or long car trip, you can do these exercises while sitting. You should also get up to walk around as much as possible.



If you go into the hospital, ask your doctor about your risk of getting blood clots. Usually, leg exercises, special stockings, or equipment can help keep the blood flowing.

In some cases, you may be given a pill or shot to thin your blood. Be sure to tell your doctor that you are taking WHI hormone study pills, so that the doctor can decide whether to continue or stop your pills while you are in the hospital. Your doctor can call the WHI clinic for more information.

Should I take WHI study pills?

Most women who are eligible to join the WHI Hormone Program are not at high risk for DVT. If you join this program and a doctor ever tells you that you have a blood clot in your legs or lungs, please notify us immediately and permanently stop taking your hormone study pills.

If you join this program, you may need to temporarily stop your hormone study pills for certain health changes, such as:

- a broken leg, hip, or back, or any other reason for having a cast on your leg
- an operation during which you are put to sleep (general anesthesia) or have an anesthetic given in your back (regional or spinal anesthesia)
- a serious injury, such as a car accident, or a burn that requires hospitalization
- a stroke or heart attack
- any severe illness that causes you to be in bed and unable to get up for more than 5 days
- any other health change that your doctor or the WHI clinic staff believes may increase your risk of blood clots

Once you are better, you should be able to start taking your pills again. The WHI clinic staff can work with you and your doctor to decide on the right time.

If you or your doctor have questions about your risk for DVT, please contact the WHI clinic at

Thank you for your interest in the Women's Health Initiative!

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Figure 3.6
What You Should Know About Deep Vein Thrombosis (DVT) [for women randomized to HRT]



WHI Update

September 1, 1997

WHAT YOU SHOULD KNOW ABOUT DEEP VEIN THROMBOSIS (DVT)

Participants in the Hormone Program of the Women's Health Initiative will be helping us to get answers to questions about heart disease, cancer, and fractures. We have developed this fact sheet to give you some information about deep vein thrombosis or blood clots. A small number of women (and men, for that matter) can develop these types of blood clots in the veins of their legs or lungs. A few recently published studies have reported that hormone replacement therapy (HRT) may increase this risk a little, but the risk is still very low. We hope this information helps you to reduce your risk of developing deep vein thrombosis.

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What causes blood clots?

Blood clotting is a normal reaction of the body. Blood clots often form because of an injury to your blood vessels (for example, a cut). Blood clots may also be caused by changes in your blood circulation. Blood circulation in your legs slows when you spend a long time in bed or are seated for many hours without moving, such as during a long plane flight or car trip.

Changes in blood clotting can also happen after a hip fracture or major operation; or when you have a severe illness, such as a heart attack, stroke, or some cancers. If you have had a blood clot in the past, you may have a higher risk of having one again. In a small number of people there is a family tendency to have more blood clots.

How will I know if I develop DVT?

Most of the time blood clots cause no problems. If the clot is small, you may not ever know you had it. Larger clots that form in the leg can cause swelling or pain of the affected leg. If both legs are swollen, it is probably not because of DVT, but you should see your doctor.

Rarely, a large clot in the leg can travel to the lung and cause a sudden shortness of breath or painful breathing. This condition is called a pulmonary embolism. Usually swelling and pain in the leg happens before shortness of breath and pain in the chest. Almost all the clots in lungs come from clots in the deep veins of the leg.

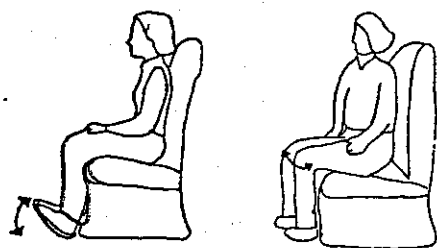
What is the role of hormones?

Studies published recently report that women taking hormone replacement therapy (HRT) can have an increased risk of blood clots in the legs or lungs. In some of these studies, the women were not as healthy as participants in the WHI or the HRT dosage was higher than the dosage used in our study. The actual risk of DVT was still much lower than that of other health problems like heart attacks or strokes.

The Women's Health Initiative will be looking carefully to see if hormones will increase blood clots in women. At this point, most women are not at risk of DVT. It is generally believed that the benefits of HRT are much greater than the risks.

How can I reduce my risk of blood clots?

Keep those legs moving! If you need to be in bed because of an illness, make sure you do leg and foot exercises several times each day (see exercises below). On a long plane flight or long car trip, you can do these exercises while sitting. You should also get up to walk around as much as possible.



If you go into the hospital, ask your doctor about your risk of getting blood clots. Usually, leg exercises, special stockings, or equipment can help keep the blood flowing.

Anytime you or your doctor have questions about your risk for DVT, please contact the WHI clinic at

Thank you again for being part of the Women's Health Initiative!

In some cases, you may be given a pill or shot to thin your blood. Be sure to tell your doctor that you are taking WHI hormone study pills, so that the doctor can decide whether to continue or stop your pills while you are in the hospital. Your doctor can call the WHI clinic for more information.

Should I stop hormone study pills?

At this time, most women in the HRT program do not need to stop their WHI hormone study pills. If a doctor ever tells you that you have a blood clot in your legs or lungs, please notify us immediately and permanently stop taking your hormone study pills.

You may need to temporarily stop your hormone study pills for certain health changes, such as:

- a broken leg, hip, or back, or any other reason for having a cast on your leg
- an operation during which you are put to sleep (general anesthesia) or have an anesthetic given in your back (regional or spinal anesthesia)
- a serious injury, such as a car accident, or a burn that requires hospitalization
- a stroke or heart attack
- any severe illness that causes you to be in bed and unable to get up for more than 5 days
- any other health change that your doctor or the WHI clinic staff believes may increase your risk of blood clots

Once you are better, you should be able to start taking your pills again. The WHI clinic staff can work with you and your doctor to decide on the right time.

Figure F.3.7.1
WHI Quick Scan Guidelines for Nutritionists

WHI Quick Scan
Guidelines for Nutritionists

The WHI Quick Scan was developed as a self-monitoring option in response to participants whose needs fit into one or more of the following categories:

- 1) **Women who have stopped self-monitoring altogether.** Certain women may respond more favorably to restarting if given the option to use a new tool.
- 2) **Those reporting "boredom" with current methods;** they may find that something new helps to regenerate interest.
- 3) **Women who request self-monitoring materials that take less time to complete** (for example, as compared to the Food Diary).
- 4) **Those finding the Fat Scan difficult or confusing to use.** For example, some participants continue to find the F/V/G columns confusing; others comment they are impatient with flipping the pages to find foods.
- 5) **Women who desire a more portable tool** (the Quick Scan folds more easily to fit into a purse).
- 6) **Those who intermittently want to use a different tool,** such as for travel.

Other considerations:

- The nutritionist may choose to ask women who consistently use the Quick Scan to complete a diary (of three or more days) at least annually in order to more easily evaluate food choices for variety and adequacy.
- The Quick Scan could be tailored to suit regional preferences by adding or substituting foods on a Master copy.
- One limitation of the Quick Scan is the limited space for tracking multiple servings of fruits or vegetables. One solution is described in the instructions for the participants; other options may be devised locally.
- The Quick Scan is to be coded as "Other" (8) as the score source on Forms 63 and 64.

Figure F.3.7.2
WHI Quick Scan Guidelines for Participants

WHI Quick Scan Guidelines for Participants

This tool is very much like the Fat Scan, except that it is only on two pages. Like the Fat Scan, the fat gram values are *averages* so that your particular food may have more or less fat than what is indicated on the Quick Scan. Simply cross out the fat grams on the form and write in the correct fat grams based on your label information.

Please start by looking at Side 1. You will see that for each food listed there is a portion size noted, as well as the fat grams, F/V, and/or grain servings for *that portion* of food.

You will see, for example, *Beans/legumes, ckd, no fat, 1/2 c*. There is a "1" in each of the Fat and Grain columns directly to the right of the bean information. This tells you that, on average, 1/2 cup of cooked beans has 1 gram of fat and counts as 1 grain serving. If you were to eat 1/2 cup of beans on Day 1, you would mark a "1" in each of the Fat and Grain columns in the "Beans/legumes" row under the Day 1 heading. Of course, if you were to eat 1 cup of beans, you would write in "2".

Three of the food entries (milk, potato, spaghetti sauce) are followed by a blank space in the Fat column. This is because the fat content of each of these foods may vary, depending on type, preparation method, or brand. The blank space is a reminder for you to determine the fat content of the product you are using, and to enter it on your Quick Scan.

A minor limitation of the Quick Scan is the amount of space available for tracking multiple servings of fruits or vegetables. One possible way to manage this is to divide the boxes into two triangles, as illustrated below. Track your fruits and vegetables throughout the day by putting little tally marks or checks in the top triangle for each serving you eat. At the end of the day, sum up the marks and put the total in the bottom triangle.

Fruits & Vegetables												
Fruit, canned, fresh, frozen, 1/2 c	0	1										
Fruit, fresh, 1 medium piece	0	1										
Vegetables, canned, fresh, or frozen, 1/2 cup	0	1										

Be sure to evaluate your progress by determining your fat, fruit/vegetable, and grain scores at the bottom of Side 2. Your average scores are figured in a way similar to the Diary or Fat Scan.

Model F.3.7.2
WHI Quick Scan

WHI Quick Scan
Side 1

Fat Goal _____ (g); F/V 5+; Grains 6+ Name _____ Week of _____

Food Item and Amount					Day 1			Day 2			Day 3		
	Fat	F/V	G	Notes	Fat	F/V	G	Fat	F/V	G	Fat	F/V	G
Breads, Cereal, Grains, Beans/Legumes													
Beans/legumes, ckd, no fat, ½ c.	1	0	1										
Bread, (1 sl), Bagel, ½	1	0	1										
Cereal, cold 1 c.; hot, ½ c.	1	0	1										
Crackers, LF, 8 med.	3	0	1										
Crackers, graham, 4 sq.	3	0	1										
Muffin, English	1	0	1										
Pancakes (2), 4" diameter	4	0	1										
Pasta/Noodles, ½ c. cooked	1	0	1										
Popcorn, no oil; 3 cups	1	0	1										
Pretzels, 1 oz. (check label)	1	0	1										
Rice, white, ½ cup cooked	0	0	1										
Roll/Bun, (1), 2 ½" diameter	2	0	1										
Dairy (check labels)													
Cheese, LF or part skim, 1 oz.	3-5	0	0										
Cottage cheese, 2%, ½ cup	2	0	0										
Frozen dessert, low fat, ½ cup	2	0	0										
Milk, 1 cup (type)		0	0										
Sour cream, low fat, 1 TB	1	0	0										
Yogurt, low fat, 1 cup	4	0	0										
Fats, Oil, Nuts, Seeds													
Butter/Marg., low fat, 1 tsp.	2	0	0										
Mayo-type spread, light, 1 TB	4	0	0										
Mayo-type spread, fat free, 1 TB	0	0	0										
Gravy with whole milk, ¼ cup	6	0	0										
Fruits & Vegetables													
Fruit, canned, fresh, frozen, ½ c	0	1	0										
Fruit, fresh, 1 medium piece	0	1	0										
Fruit, dried, ¼ cup	0	1	0										
Fruit juice, 6 oz.	0	1	0										
Potato, baked, 1 medium	0	2	0										
Potato, ½ cup, preparation?		1	0										
Vegetables, canned, fresh, or frozen, ½ cup	0	1	0										
Salad, tossed, 1 cup	0	1	0										
Subtotal													

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Model F.3.7.2
WHI Quick Scan (Continued)

WHI Quick Scan, Side 2

Name _____

Food Item and Amount	Fat	F/V	G	Notes	Day 1			Day 2			Day 3		
					Fat	F/V	G	Fat	F/V	G	Fat	F/V	G
Meat, Eggs, Fish and Poultry													
Beef, ground, diet lean, 10% fat, OR trimmed T-bone, 3 oz.	8	0	0										
Beef, round, rump, sirloin, trimmed, 3 oz.	4	0	0										
Chicken, Turkey, no skin, light meat, 3 oz.	3	0	0										
Chicken, Turkey, no skin, dark meat, 3 oz.	7	0	0										
Egg, 1 large, whole	5	0	0										
Fish, low fat, white, 3 oz.	1	0	0										
Ham, cured, trimmed, 3 oz.	8	0	0										
Hot dog, very LF or FF, 1	0-1	0	0										
Lunch meat, 95% FF, 1 oz.	2	0	0										
Pork, loin, trimmed, 3 oz.	9	0	0										
Tuna, in water, 3 oz.	0	0	0										
Mixed Dishes and Soups													
Chili, reg., w/meat, and beans, 1 cup	13	½	1										
Lasagna, 3x3", with meat	14	½	1										
Meatloaf, 4 ½ x 2 ½ x ½"	12	0	0										
Pizza, 1/8 of 14", 1 sl cheese	8	0	1										
Spaghetti sauce, w/meat, 1 cup	19	1	0										
Spaghetti sauce, commercial, 1 cup (check label)		2	0										
Sweets and Desserts													
Brownie, 2 ½" sq., no nuts	16	0	1										
Cake, 3x3x2", reg, w/icing	24	0	1										
Cookies, 1 lg, 2 med, or 3 sm, high fat; <i>or</i> see label	6 to 12	0	1										
Pie, 1/6 of 9", single, fruit	15	0	1										
Pie, 1/6 of 9", dbl crust, fruit	29	0	2										
Other													
					Fat	F/V	G	Fat	F/V	G	Fat	F/V	G
Subtotal (from this side)													
Subtotal (from other side)													
How Did I Do? Total													

Scores*: Fat Fruit/Vegetable Servings Grain Servings

*(Day 1 + Day 2 + Day 3) + 3 = Score for each of your WHI goals

Figure F.3.8
WHI Picture Tracker Instructions

Picture Tracker Instructions:

Each time you eat a serving of fruit, circle the "apple." Each time you eat a serving of vegetables, circle the "broccoli." Each time you eat a food made from grains or beans, circle the "wheat."

*** Guidelines to Estimate Serving Sizes ***

One Fruit/Vegetable Serving:

1 medium piece of fruit	1 cup raw leafy vegetable (like lettuce)
1/2 cup chopped fruit	1 cup cooked or raw vegetables
3/4 cup 100% juice	1/2 cup potatoes or squash
1/4 cup dried fruit	1 4-inch long baked potato

One Grain Serving

1 slice bread or 1 hamburger bun	1/2 bagel or 1 whole English muffin
1/2 cup cooked cereal or grits	1 cup cold cereal
3 cups popped popcorn	6 to 8 small crackers
1/2 cup cooked pasta or noodles	2 medium (3-inch round) cookies
1/2 cup cooked dried beans or peas	1/2 cup cooked rice or other grains

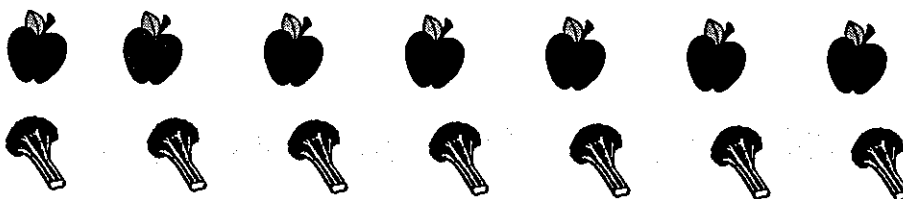
More detailed serving size information is in the Fat Counter on pages 11, 12 and 13.

Figure F.3.8
WHI Picture Tracker

Women's Health Initiative Picture Tracker

Name: _____ Date: _____ Day: _____

5 or more Fruits/Vegetables – Circle



6 or more Grains - Circle



Low fat foods eaten...

_____	_____
_____	_____
_____	_____

High fat foods eaten...

_____	_____
_____	_____
_____	_____

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Figure F.3.9
WHI Update – What You Should Know about the “HERS” Study



WHI Update

October 1998

WHAT YOU SHOULD KNOW ABOUT THE “HERS” STUDY

Thank you for participating in the Hormone Program of the Women's Health Initiative (WHI). You are helping us to get answers to questions about heart disease, cancer and fractures. From time to time, results from new studies become available. It is our goal to keep you informed of these developments. We have prepared this fact sheet to keep you up to date about new medical information from another study and how it relates to your participation in WHI.

What is HERS?

HERS stands for the Heart and Estrogen/ Progestin Replacement Study. This study was designed to look at the effect of hormone replacement therapy on the rate of recurrent heart problems in women who already had heart disease.

How is WHI different from HERS?

HERS is very different from the WHI. In all, HERS had 2,763 participants, while the WHI Hormone Program has over 27,000 women.

The HERS study included only women who had previous heart disease. The WHI Hormone Program includes women with and without previous heart disease. HERS also studied only estrogen and progestin in women who still had their uterus. The WHI Hormone Program is studying either estrogen and progestin or estrogen alone based on whether women do or do not have a uterus. Thus, less than 2% of the WHI Hormone Program participants would possibly have qualified for HERS.

The WHI Hormone Program is looking at the long-term effects (up to 12 years) of hormones on heart disease and many other health problems (for example, fractures, breast and endometrial cancers). HERS

followed participants for only 4 years on average, which was not long enough to study some of these other health problems. The WHI as a whole will answer many other important questions including the effect of diet on breast and colon cancer or the effect of calcium and vitamin D on fractures and colon and rectal cancer. Many WHI Hormone Program participants are taking part in these other WHI programs as well.

What did the HERS trial show?

The HERS trial found that taking estrogen plus progestin for up to 4 years did not prevent further heart attacks or death from previous heart disease in postmenopausal women who already had a previous heart attack or known heart disease. This neutral finding occurred even though there was a good effect of treatment on cholesterol.

For the entire four-year HERS trial period, there were no significant differences in heart problems between the active hormone and the placebo groups. In the first year of HERS, the active hormone group did have somewhat more heart problems than the placebo group, but after 2 or more years the active hormone group had somewhat fewer heart problems.

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As expected, HERS did show that women taking active hormone had an increase in problems with blood clots and a small increase in gallbladder disease. We have previously informed you of these risks of hormone therapy. Long-term studies like the Women's Health Initiative are needed to more fully understand both the short and long-term effects of estrogen on heart disease, and to learn how the overall benefits and risks of hormone replacement therapy balance out.

How do the HERS findings affect my participation in WHI?

In sum, the HERS findings do not change the importance of WHI or the importance of your ongoing participation in the program. HERS has taught us about the 4-5 year effects of starting hormones in women who already have heart disease. The vast majority, about 98 percent, of the women in WHI do not yet have heart problems. WHI is crucial for providing answers about

whether hormones prevent heart disease in healthy women.

For women with known heart disease, the HERS investigators do not recommend that these women start hormones to prevent future heart problems. However, for women with heart disease who are already on hormones, the HERS investigators recommend that they could continue the hormones. This is because of the possible benefit after longer treatment. Similarly, the WHI investigators recommend that you continue if you are already in the WHI Hormone Program, so that we can learn more about the long-term effects of hormones.

Following publication of the HERS results, there is widespread agreement that there is a critical need for WHI and other randomized trials of hormones to give us more complete answers about long-term effects on women's health. You are helping us to find those answers, and your ongoing participation in the WHI Hormone Program is more important than ever!



If you or your doctor have questions about this information, please contact the WHI clinic at:

Thank you for continuing to be a part of the WHI!

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Figure F.3.10
WHI Update – What you should know about: SERMs



What you should know about: *SERMs*

Have you seen newspaper or magazine articles about new “estrogen-like” medications called Selective Estrogen Receptor Modulators or SERMs? In 1998, the Food and Drug Administration approved the release of one of these medications, raloxifene (Evista™). We would like to bring you up to date about SERMs and the Women’s Health Initiative.

What’s so new about these medications?

You may recall that estrogen acts on many parts of your body, including your bones, breasts, uterus, and blood system. SERMs act on your body too, going to the same parts that estrogen does. However, SERMs appear to have different (more selective) effects.

In 1998, a SERM known as raloxifene (Evista™) was approved by the Food and Drug Administration for the prevention and treatment of osteoporosis in postmenopausal women. We expect other SERMs to be approved in the future. Studies of raloxifene show that it prevents bone loss in the spine and hip (although this benefit is less than that from estrogen). Raloxifene also appears to improve some blood lipids (cholesterol) that have been related to the risk of heart disease. However, raloxifene also affects clotting factors in the blood and increases a woman’s risk of blood clots in the legs and lungs, similar to estrogen. Long-term information on raloxifene is limited because it has only been studied for a few years. At this time, raloxifene does not appear to affect the lining of the uterus. We are also not certain of its effect on the breast. Raloxifene may decrease breast cancer risk

or at least slow down the early growth of breast cancer, but further studies are needed. It does not relieve “hot flashes” or other menopausal symptoms; and in fact it may increase hot flashes.

Will the Women’s Health Initiative start using these new medications?

WHI does not plan to use SERMs. The scientific information on raloxifene is very new and based on only a few years of experience in postmenopausal women. Much more research is needed on the long-term safety of SERMs.

The Hormone Program of the Women’s Health Initiative is a 12-year scientific research study of estrogen—a female hormone that has been widely used by postmenopausal women for over 40 years. Although smaller, short-term studies do show possible benefits from estrogen, we do not know as much about the long-term benefits or risks. We still need answers about the long-term effects of estrogen on heart disease, osteoporosis, and breast cancer. These answers must come from large, long-term, scientific clinical trials, like the Hormone Program of the Women’s Health Initiative.

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What if my health care provider recommends SERMs?

Taking raloxifene, or other new SERMs that may come out, is a decision to be made by you and your own health care provider, based on your health needs. If you are in the Dietary, Calcium and Vitamin D, or Observational Programs, taking SERMs will not affect your participation in WHI.

If you are in the WHI Hormone Program, you will need to stop your study pills when you take raloxifene or other SERMs. Information on the safety of using female hormones with SERMs is not yet available. If you or your health care provider are thinking about raloxifene (Evista™) or other SERMs to prevent osteoporosis, there are other medications—such as alendronate (Fosamax™) or calcium—that you can take and stay in the Hormone Program. If you try SERMs and decide they are not for you, you can re-start your study pills.

We hope that you will stay with the WHI. You are already helping to find answers to many questions we have about women's health. It is important that all WHI participants stay in the study, even if they stop study pills. By continuing to work together, we will have the information we need to answer the long-term questions about women's health.

Your WHI clinic staff cannot take the place of your own health care provider, but we can answer general questions you might have about SERMs and WHI. Please feel free to contact us at:

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Figure F.3.11

WHI Update – What you should know about: Osteoporosis



What you should know about: *Osteoporosis*

We have developed this fact sheet to give you some information about osteoporosis (bone loss or “porous” bones). We all experience some bone loss as we age. Bones reach their greatest strength around age 20-35. Women tend to have bone loss later in life, at the time of menopause. Because weak bones are more likely to fracture or break, osteoporosis can greatly affect your health. One health goal is to prevent bone loss and even rebuild bone, especially after menopause. We hope the following information helps you learn more about this common condition and how it can be prevented and treated.

What is osteoporosis?

Osteoporosis is a condition in which bones become fragile and more likely to break, especially in the hip, spine, and wrist. Loss of height, rounding posture, and tooth loss are also linked to osteoporosis. Nearly half of all women now age 50 will someday have a broken bone due to osteoporosis.

How is the WHI finding answers about preventing bone fractures and osteoporosis?

The Women’s Health Initiative (WHI) is studying whether taking calcium and vitamin D supplements reduces the number of hip and other bone fractures in postmenopausal women. Hip fractures are a major cause of disability in older women. Many people think that calcium and vitamin D supplementation will help reduce fractures, but this has not been proven. WHI offers a unique opportunity to prove whether these supplements are worth taking for many years. WHI has shown that combined estrogen plus progestin therapy prevents fractures. But it also increased the risk of heart attack, stroke, blood clots, and breast cancer. Therefore, the fracture benefit needs to be balanced against these risks when choosing a medicine for your osteoporosis. It is not known if taking estrogen alone will have the same results. The estrogen alone WHI study is continuing.

How do I know if I have osteoporosis?

A sign of osteoporosis is having a fracture after a simple fall. The diagnosis of osteoporosis is sometimes made by using one of a number of painless tests that measures the amount of bone mass and predicts the risk for fracture. One of the most commonly used techniques is a bone density test of the spine and hip. It is considered the “gold standard”.

The U.S. Preventive Services Task Force

recommends that women 65 years of age or older have a routine bone density test for osteoporosis. Women aged 60 to 64 should have a bone density test if they have an increased risk of fractures. Women under age 60 should check with their doctor about the need for bone density screening. As with any health condition, talk with your doctor if you think you may have osteoporosis. He/she can talk with you and decide if testing is needed.

Who is at risk for osteoporosis?

Risk factors for osteoporosis are:

Gender: Women are more likely than men to develop osteoporosis. Women have less bone and lose it faster than men as a result of menopausal changes. Women also tend to live longer than men, and older age is a risk factor for osteoporosis.

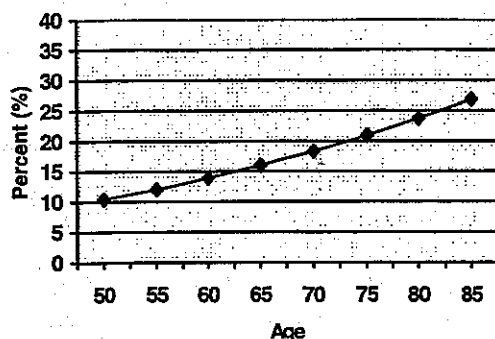
Race: Caucasian and Asian women are at highest risk for developing osteoporosis.

Body type: Small-boned and thin women are at greater risk.

Family history: Risk of fracture may run in families. If your mother had bone fractures, you may also be at risk for lower bone mass and fractures.

Age: The older you are, the greater your risk of osteoporosis. It is most common in women after menopause. The following chart shows that women with osteoporosis at age 50 have about a 10% chance of having a fracture over the next 5 years. Women with osteoporosis at age 80 have over twice that risk, or nearly a 25% chance of having a fracture over the next 5 years.

5-Year Risk of Fracture in Women with Osteoporosis



Past History of Fracture: Women who have already experienced a fracture are at a very high risk of suffering additional fractures. This is one of the strongest risk factors.

Lifestyle: Smoking, heavy alcohol use, and not getting enough calcium or exercise increase the chance of developing osteoporosis.

If you are at risk for osteoporosis, some guidelines you can follow include:

- **Eat a balanced diet rich in vitamin D and calcium.** Vitamin D helps your body absorb calcium. Your skin makes vitamin D when it is exposed to sunlight. Vitamin D is also found in certain supplements and enriched milk. Dairy products are a good source of calcium.
- **Exercise.** Establish a routine that includes regular weight-bearing exercises, like walking, jogging, or dancing. Active bodies are better able to use calcium for building and keeping strong bones. These activities also make muscles stronger and improve balance, so that you are less likely to fall and break a bone. Before starting an exercise routine, be sure to ask your doctor what is safe for you.
- **Maintain a healthy lifestyle.** Don't smoke. Limit alcohol intake to no more than 1 or 2 drinks per day.
- **Prevent falls and make your home safer.** Most hip fractures happen as the result of a fall. Remove clutter, secure rugs, and use grab bars and non-skid tape in the tub or shower. Keep rooms, halls, stairways, and entrances well lit, and wear sturdy, non-slip shoes.

How is osteoporosis treated?

There are several medications approved by the FDA to prevent and treat osteoporosis. They can slow or stop bone loss, increase bone density, and reduce fracture risk. Alendronate (Fosamax®), risedronate (Actonel®), raloxifene (Evista®), calcitonin nasal spray (Miacalcin®), and teriparatide (Forteo®) are all approved to treat osteoporosis. If you are in the WHI Estrogen Alone study, you cannot continue your study pills if you take raloxifene (Evista®).

Therefore, you might ask your doctor about taking one of the other anti-osteoporosis drugs. The decision to use any medication should be made with your doctor, who can review the benefits and risks for your own situation.

How do calcium and vitamin D help?

Getting enough calcium through diet or supplements may help maintain bone strength.

For postmenopausal women, a calcium intake of 1,200 mg each day is considered adequate (Source: Institute of Medicine, Food and Nutrition Board).

Vitamin D increases the amount of calcium absorbed in the body. For postmenopausal women, a vitamin D intake of 400 to 600 International Units (IUs) each day is considered adequate.

Currently, it is not known if calcium and vitamin D can prevent hip fractures, the most devastating fracture associated with osteoporosis. This is one of the important questions for WHI to answer.

How much calcium and vitamin D is recommended and how much is too much?

Up to a certain limit, your body will not absorb more calcium than it needs. A calcium intake up to 2,500 mg each day is probably safe and is more than you would normally get from foods and supplements.

Unlike calcium, you can take too much vitamin D. However, up to 2,000 IU each day is probably safe and is more than you would get even if you were taking your own supplement and WHI study pills containing vitamin D. However, we do ask you to limit your vitamin D intake to 1,000 IU if you are in the WHI Calcium/Vitamin D Trial.

The WHI will be answering important questions about calcium and vitamin D, osteoporosis, and bone fractures. Thank you for your interest in this important area of health research.

Figure F.3.12
WHI Update – WHI Today



WHI Update

WHI Today

2000

Over the past five years, more than 160,000 women across the U.S. have joined forces with WHI doctors and scientists to learn more about women's health. This is a tremendous achievement and we want to thank you for joining the Women's Health Initiative and for your continued involvement!

During the current phase of the study we are continuing to collect and analyze follow-up data. When you come in for follow-up visits, complete forms, and give blood samples, you are providing the information we need to find important answers about women's health.

So far, an impressive 93% of you enrolled in the Dietary or Hormone Replacement programs and 85% in the Observational Study have attended follow-up visits on schedule. Nationwide, WHI participants have completed over 380,000 follow-up visits, given nearly 265,000 blood samples, and completed 4.6 million questionnaires. Keep up the good work! The more data we have, the more accurate the results, so staying with the study to the end in 2005 is very important. We look forward to seeing you in the years to come!

The Women of WHI

Now that enrollment in WHI is complete, we can start looking at characteristics of the women in the study. The box at right contains a brief profile of all women enrolled in WHI. We will keep you up-to-date on other study results as they become available.

A Brief Profile of WHI Participants

Family and Friends

- 4% of you have never been married
- 62% are married or living as married
- 16% are divorced or separated
- 17% are widowed
- 25% live alone
- 41% help a sick or frail family member or friend on a regular basis
- 41% have a pet
- 37% are currently employed outside the home
- Nearly 3% have served in the U.S. armed forces

Health

- 75% consider yourselves to be in very good or excellent health
- 94% have a health care provider
- 51% have never smoked
- 42% have quit smoking
- 76% usually get some moderate or strenuous physical activity each week
- 42% have had a hysterectomy
- On average, sleep 6.9 hours per night

Many of you have been diagnosed with medical conditions, including:

- 14% with high cholesterol
- 34% with high blood pressure
- 4% with diabetes

The Women's Health Initiative is supported by the National Institutes of Health, under the leadership of the National Heart, Lung, and Blood Institute. Visit our website at <http://www.nhlbi.nih.gov/whi>

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WHI Science

The main goals of WHI are to look at the role diet, hormone therapy, and calcium and vitamin D may play in preventing heart disease, breast and colon cancer, and osteoporosis. We do not expect to know the answers to these important questions until the end of the study, around the year 2005. At that time, we will have collected all the necessary data and be able to see the results of your efforts--results that are eagerly awaited by women, doctors, and scientists everywhere.

Until then, we are using the WHI data already collected to study hundreds of other issues related to women's health. For example, WHI scientists are now in the process of preparing research reports on the following topics:

- Factors associated with treatment and control of high blood pressure
- Psychological factors related to alcohol use
- Insurance coverage and cancer screening
- Relationship between smoking and weight
- Factors associated with sleep complaints
- Physiological factors related to depression
- Factors associated with hip and knee replacement
- Passive smoke exposure and heart disease
- Social support and cancer screening
- Diet, physical activity, and exercise among women with diabetes

As you can see, the information you provide is giving researchers a broad range of topics to study. In addition to the papers in progress, several papers describing the design and goals of WHI have already been published in scientific journals. This landmark study is also frequently mentioned at scientific meetings and in reports by researchers everywhere who eagerly anticipate the final results.

Your Safety Matters: Keep in mind that your safety is always our primary goal. To protect you and all women participating in WHI, an independent group of experienced

medical experts meets every six months to review WHI results. This group, called the Data and Safety Monitoring Board, reviews study results to make sure that it is still safe for you to participate. Though we expect it will take several years to understand the role of diet, hormones, and calcium and vitamin D on women's health, the investigators and staff at your WHI Clinical Center will do everything they can to assure your safety and that your efforts will lead to important answers about women's health.

WHI in the News

Since the earliest days of the study, many local and national news programs and publications have regularly featured reports about WHI. Hundreds of newspaper articles, magazine articles, and television programs have made WHI a national focus. As we continue in the follow-up phase, WHI is still often featured in articles about women's health. These articles help remind women and their health care providers that this one-of-a-kind study will provide answers to some of the most crucial health issues facing women today. For example, WHI was recently mentioned in two national magazines:

- *The New Yorker* (10/11/99), in a special feature on women's health, described WHI as leading the way in the recent surge of national studies aimed at reducing health risks in older women.
- *Newsweek* (Special Issue - 3/1/99) ran a story on Dr. Bernadine Healy, the former director of the National Institutes of Health, who helped launch the Women's Health Initiative. In the article, Dr. Healy discusses the tremendous scope and importance of WHI.

This attention highlights the fact that women across the U.S. and around the world may someday benefit from *your* efforts today. Thanks again to each and every one of you!

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Figure F.3.13
WHI Update – Health Follow-up by Proxy



WHI Update

Health Follow-up by Proxy

One of the most important goals of the Women's Health Initiative (WHI) is to keep track of any major changes in your health through the end of the study. This information is critical for answering scientific questions about women's health. You, of course, are the best source of information about your health. However, there may come a time when you are not able to provide these details yourself because of major health changes. That is why we are asking you to provide us with the name of someone who can answer questions about your health if you cannot. This person is called a proxy.

What is a proxy?

A proxy is someone who can "stand in" for you and tell us about your health when you cannot because of serious illness or death.

Why is a proxy needed?

For many years, you have been answering important questions about your health for WHI. These answers should not be lost, even if you are not able to provide them.

What does a proxy do?

We will ask your proxy to answer questions only about your health, just like the questions you already answer every year on your medical history update. For example, the proxy may tell us where and when you were in the hospital or about a recent illness you have had. Your proxy might also be asked to sign a medical release, just as you have done. A current release would be needed so WHI can obtain the most recent medical information from your health care provider.

Who should be named as proxy?

This is your decision. You should select someone who knows you well enough to tell us if you have had health problems or have been in the hospital. In order to provide the best responses to health questions about you, your proxy should be someone you live with, or visit or talk with by phone at least twice a month. For example, you might name your legal next of kin (spouse, son or daughter, brother or sister), a trustee named in your will, the person who has medical power of attorney, or your doctor.

Can I change my proxy?

Yes, you can change your proxy, at any time. At your annual clinic visits or contacts we will ask you to review and update your personal information sheet. This sheet includes your proxy's name and contact information. At that time you can change your proxy. You can also call us anytime with the name of a new proxy.

Will you give my proxy information about me?

No, all information you provide is strictly confidential and will not be shared with your proxy.

Will you tell any of my friends or family who my proxy is?

No, we will not tell your friends or family members who you've named as proxy. Of course we ask you to inform your proxy and you are welcome to share this information with others, but we will not.

Is this a change in the study?

We have always been interested in obtaining your medical records when you have a health event. These records help us see if you have had a broken bone, cancer, or heart problems while you are in WHI. This information helps us evaluate the impact of the WHI program you are a part of. When you signed the consent form at the beginning of the study, you gave us permission to

obtain these records. We are now asking you to name someone who can help complete this job for you if you cannot.

What would you like me to do now?

- Please think about the people in your life and choose who would be the best proxy for you at this time. We will be asking you to provide us with the name and contact information for that person, either at your clinic visit or by mail.
- Place a copy of this update with your other important papers to remind those close to you of your participation in WHI.
- You will be given a second copy of this update and a letter explaining the purpose of WHI. Please give or mail the letter and update to the person you name as your proxy. These materials will help your proxy understand your commitment to WHI and their special role in the study.

Thank you for your continued participation in WHI. The information you provide is critical in helping answer important questions about women's health!

F.3.14
Proxy Letter



Dear _____,

As you may know, I am a participant in the Women's Health Initiative (WHI). This important health study includes over 160,000 women across the U.S. The purpose of this study is to learn more about postmenopausal women's health and about the ways to prevent certain diseases in women.

I am asked to fill out a few forms about my health each year throughout the study. The information is collected to help WHI find answers to important questions about women's health. However, there may come a time when I cannot provide this information myself because of a serious illness or disability. I have chosen you to serve as my proxy (personal contact) to answer questions about my health, in case I cannot provide this information myself. If you are ever contacted by someone from WHI, please answer their questions regarding my health. For example, they may ask you if I had any hospitalizations or serious illnesses in the previous year. You may also be asked to give permission to my physician or hospital to release some of my medical records to WHI staff.

I strongly believe WHI should receive information about me, even if there comes a time when I am not able to provide it. I want you to be assured that answering questions in my place is something I want you to do. I know it is very important for WHI to have complete follow-up information on everyone. This information is essential so that the WHI results are accurate and trusted by scientists and physicians. The information you provide to WHI will be kept strictly confidential and will not be shared with anyone outside of the study.

I want to thank you for your willingness to help make the Women's Health Initiative a success! If you have any questions about the study or your role as a proxy, you can contact WHI staff at the telephone number listed below. With your help, WHI will have information that is vital for the study to succeed. Together, you and I can contribute to the health of all women for generations to come.

Warmest regards,

Signature

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Figure F.3.15
CaD Handbook

THE WOMEN'S HEALTH INITIATIVE

Calcium/Vitamin D Handbook

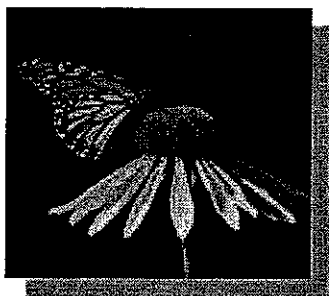


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CALCIUM/VITAMIN D HANDBOOK

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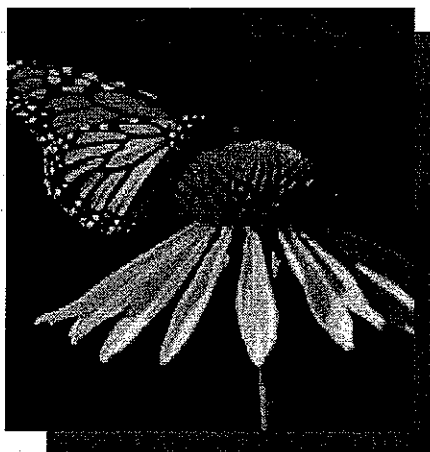
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More/Further Questions?	<i>Inside back cover</i>

Figure F.3.15
CaD Handbook, con't

2

THE WOMEN'S HEALTH INITIATIVE



The WHI Calcium/Vitamin D Program – Your Participation is Important

Congratulations and a great big “THANK YOU” for completing another year in the Women’s Health Initiative Calcium and Vitamin D (CaD) Program! It is an exciting time for women’s health research. You should be proud that your participation in WHI might help other women live healthier, more active lives.

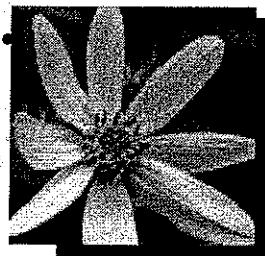
With all of the new advances being made in disease prevention and treatment, it is sometimes easy to overlook how simple lifestyle habits may affect our health. Although research suggests that taking calcium and vitamin D may help prevent bone fractures or reduce the risk of colon cancer, this has not been proven. Your commitment to the WHI CaD Program will help us understand whether these common supplements actually do prevent fractures or reduce the risk of colon cancer.

Figure F.3.15
CaD Handbook, con't

CALCIUM/VITAMIN D HANDBOOK

3

Calcium and Vitamin D – A Healthy Duo?



Calcium and vitamin D are believed to work best in combination. Most calcium comes from our diet and is stored in our bone. Vitamin D helps the body absorb calcium. It is known as the “sunshine vitamin” because our bodies make vitamin D after we are exposed to sunlight. Current recommended intakes of calcium and vitamin D vary by age. The National Academy of Sciences recommends that adults, ages 51 and older, consume 1200 mg of calcium each day. Experts also recommend a daily intake of 400-800 International Units (IU) of vitamin D, which people can get just through regular sunlight exposure. In order to meet these recommendations, your diet should be rich in calcium-containing foods. The best sources of dietary calcium are dairy products, calcium-fortified juices, or calcium-processed foods. Examples are milk, evaporated milk, yogurt, calcium-fortified orange juice, and firm calcium-processed tofu. Cheese, cottage cheese, cooked dark green leafy vegetables, calcium-fortified cold cereals, baked beans, and

fish canned with bones (such as salmon or sardines) contain moderate sources of calcium. Vitamin D fortified milk is the best food source of vitamin D. Only about one-third of the calcium we take in is actually absorbed. Factors such as older age, certain medications, stomach or bowel problems, or liver or kidney diseases can decrease calcium absorption even more. Healthcare providers will sometimes recommend that people supplement their diets with calcium and vitamin D if they have decreased calcium absorption and cannot get enough calcium from dietary sources.

The recommended intakes above are for your health in general. We do not know if these amounts of calcium and vitamin D will prevent bone fractures or colon cancer. The WHI Calcium and Vitamin D Program was specifically designed to find out if calcium and vitamin D supplements prevent bone fractures or colon cancer. Your participation in this program is also helping us to understand how calcium and vitamin D supplements affect other chronic diseases in women.

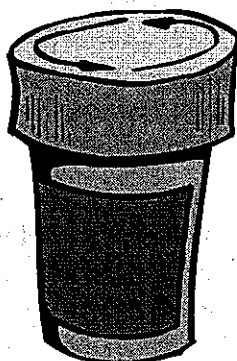
Figure F.3.15
CaD Handbook, con't

4 THE WOMEN'S HEALTH INITIATIVE

What Should I Be Doing in the Calcium and Vitamin D Program?



Using a computer, you and over 35,000 other women participating in the CaD Program were selected by chance to take either active calcium and vitamin D study pills or placebo (inactive) pills. This kind of "randomization" is critical for answering scientific questions about calcium and vitamin D. Neither you nor the research staff knows what type of pills you are taking. You may continue to eat your normal foods and take your own calcium supplements while you take the WHI study pills. The routine you have been asked to follow for the CaD Program is fairly simple:



Take one study pill twice a day with a meal.

- A good schedule would be to take one study pill with breakfast and one with dinner.
- You can choose between two types of study pills—ones you can chew and others you can swallow.
- The chewable tablets taste like peppermint and can be chewed by themselves or broken up into small pieces and mixed with food or water.
- The study pills you swallow are a little smaller and can be taken whole with water, like any other pill.
- You do not need to limit your own calcium intake, even if you have been assigned to the active study pill group.

Be careful with your own intake of vitamin D.

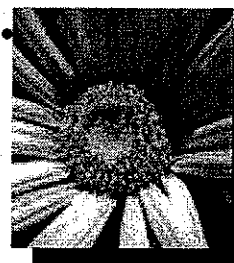
- If you take vitamin D in addition to your study pills, you should take no more than 1000 IU each day.
- You will get some additional vitamin D in your diet, which is fine.

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CaD Handbook, con't

CALCIUM/VITAMIN D HANDBOOK

5

Challenges in Taking Calcium and Vitamin D Study Pills



"I Can't Remember to Take My Pills!"

One of the big challenges in taking your study pills is just remembering to do so each day. There are a number of memory "joggers" you can use to help you remember to take one study pill twice a day. A calendar, pill organizer or other gadget that tracks each day may help. You might try to establish a routine, such as taking your pills at the same time each day or with a certain meal. Whatever you do, taking your study pills should become a regular part of your day, much like brushing your teeth or taking medications prescribed by your healthcare provider. The WHI staff can offer other suggestions if you do not always remember to take both pills each day.

"I Don't Like to Take These Study Pills Because..."

Flavor/Texture

If you do not like the taste or texture of the chewable tablets, there are other ways to take them. You can break them into smaller pieces and swallow them, mash them up with a soft food

such as applesauce or hot cereal, or even add them cut or crushed to water or juice. We also have a study pill that you can swallow, and you may switch to this kind of pill at any time. You would take one of these pills twice a day, just like the chewable ones.

Side Effects

Side effects or symptoms are usually minor and not all women will experience them when they are taking study pills. Side effects may be different for each person and changes in symptoms may not be caused by the study pills at all. Symptoms like bloating, gas, stomach upset, or constipation, in general, are common in older women.

Gas and Bloating

Some people feel very gassy or bloated after eating certain foods, drinking carbonated water, chewing gum, or when they are under stress. The type of calcium chosen for this study is usually well tolerated, but there are steps you can take if you have gassy or bloated feelings:

Figure F.3.15
CaD Handbook, con't

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THE WOMEN'S HEALTH INITIATIVE

- Take your study pills with meals.
- Drink lots of water or other fluids to help break up gas and move it more quickly through your system.
- Use simethicone, which also helps to break up gas. This medicine can be found in drug stores, often sold as Mylicon® or Gas-X®.
- Wear clothing with a loose waistline.

Stomach Upset/Heartburn

Like other kinds of symptoms, many things other than the study pills, such as the foods we eat, can be caused by an upset stomach or heartburn. In fact, many over the counter medicines for these problems have calcium in them. Try some of the following to relieve your symptoms:

- Take your study pills with a full glass of water to wash them down well.
- Take your study pills with meals, so that they mix up well with everything else in your stomach.
- Sit up for an hour after meals and try not to eat for an hour or more before bedtime.

*Constipation*

Constipation is a common problem as we get older. It can be caused by the food we eat, the amount of fluid we drink, or how physically active or inactive we are. The exact cause of constipation is usually hard to find, and it may not be related to the study pills at all. The form of calcium we are studying in WHI was chosen because it is usually well tolerated. However, if you experience constipation, here are some things that might help:

- Increase the amount of fluids you drink – the more water you drink, the more liquid is available to soften your stool.
- Increase the amount of roughage you eat, like fresh (not cooked) fruit and vegetables, prunes and prune juice. Be sure to drink plenty of fluids with these foods.
- Take a mild stool softener (available in drug stores) for a few days.

Kidney Stones and Hypercalcemia

Very rarely, taking a lot of calcium may be associated with kidney stones or a condition called “hypercalcemia” – high blood levels of calcium. Please call the WHI clinic if your personal health care provider says you have kidney, bladder, or urinary tract stones or high levels of calcium in your blood.

Figure F.3.15
CaD Handbook, con't

CALCIUM/VITAMIN D HANDBOOK

7

Frequently Asked Questions



Calcium

“Why is it all right with WHI if I keep on taking my own calcium?”

Many women know that taking calcium is good for your health in general, so you may already have a diet high in calcium or take calcium supplements. The amount of calcium women usually take to stay healthy is safe, even when they are taking CaD study pills. Even if you take calcium for your general health, we are confident that we can answer the WHI study questions about CaD, bone fractures, and colon cancer. In fact, WHI scientists will be able to study the effects of taking higher doses of calcium compared to lower doses

“How much calcium is too much? Is it possible to take too much?”

WHI scientists carefully reviewed the studies on this question and could not find good evidence for setting an upper limit of calcium intake for women in the CaD Program. Our bodies adapt to taking a large amount

of calcium at once by not absorbing as much. Women have asked if a higher calcium intake causes kidney stones or high blood calcium, but this has not been proven scientifically.

“How will the study be able to test the effects of calcium if I am taking my own as well?”

We ask you every six months how much calcium you are taking on your own. This amount is entered into the computer, which also knows if you are taking the active (calcium and vitamin D) or inactive (placebo) study pill. The computer can then figure out the total amount of calcium you are taking. When we analyze this information, we will learn about the effects of a wide range of calcium intakes on fractures and colon cancer.

Figure F.3.15
CaD Handbook, con't

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THE WOMEN'S HEALTH INITIATIVE

■ *"Can I get enough calcium if I don't eat dairy foods?"*

While dairy foods provide 75 percent of all the calcium in the U.S. food



supply, there are many other foods that provide large amounts of calcium. For ideas about non-dairy food sources of calcium, please look at the WHI handout, *About Calcium in Your Diet*. Your clinic staff can give you a copy of this handout, if you no longer have one.

■ *"Should I take a calcium supplement?"*

Health and nutrition experts recommend that you should try to get your daily recommended calcium by eating enough calcium-containing foods and by selecting a diet that contains a variety of foods. Many of these foods contain other nutrients that work with calcium to keep your bones healthy. If you use a supplement instead of eating foods with calcium, you may not get enough of the other important nutrients.

Vitamin D

■ *"Why do I have to limit the amount of vitamin D I take?"*

Unlike calcium, you can take too much vitamin D. Very high doses of vitamin D may cause high blood calcium levels, although this has not been shown in strict scientific studies. WHI scientists have chosen 1000 IU as a cutoff to ensure that you would not be getting too much vitamin D, even if you are taking your own vitamin D and the active study pills. Actually, up to about 2000 IU of vitamin D per day is probably safe. This amount is likely to be far more than you would ever get, even if you were taking the active study pills and your own supplements.

■ *"Do I need to limit the food I eat or the milk I drink if it has a lot of vitamin D in it?"*

No. Most foods you eat, even if fortified with high amounts of vitamin D, will result in only small amounts of vitamin D in your body. The WHI requires that you keep your own vitamin D supplement use to 1000 IU or less.



Figure F.3.15
CaD Handbook, con't

CALCIUM/VITAMIN D HANDBOOK

9

CaD Study Pills

■ *"What are the pills made of? I have to watch my sugar and salt intake."*

We have a list of study pill ingredients that we can show you. In general, each study pill averages 10 calories. At most you would get about 2 grams of sugar and a very small amount of salt (less than 136 mg) in each pill. Please call your WHI clinic if you are allergic to anything that is commonly used in pills. The active ingredient in the active CaD study pills is calcium carbonate, chosen because it is widely available and is absorbed well by the body.

■ *"Can I take both pills at once? I always forget to take the second one."*

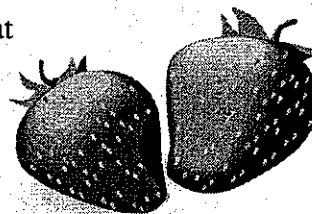
It is best if you can take one pill at two different times each day because the body can better absorb smaller amounts of calcium at a time. If you find that you forget your pills regularly, the clinic staff can work with you on ways to remember to take them. If these ways do not help, however, it is better to take both study pills at the same time each day than to take only one pill a day.

■ *"Does it matter if I take my Calcium/Vitamin D study pill with or without food?"*

Experts agree that calcium is best absorbed when taken with food.

Food helps to provide enough acid to help your body take in or absorb the calcium.

Taking your study pills with food can also help prevent some of the gassy and bloating feelings some people may have. Although we've asked you to take your study pills with meals, it is not a requirement. You can take your study pills without food, if you tolerate that well.



■ *"Can I take my Calcium/Vitamin D study pills with other vitamins, supplements, or medications?"*

In most cases, you will be able to take your CaD study pills with other vitamins, supplements, or medications. However, there are a few exceptions.

Figure F.3.15
CaD Handbook, con't

10 THE WOMEN'S HEALTH INITIATIVE

Medications

Calcium may interfere with the absorption of certain medications. It is important for you to review with your doctor whether the absorption of a medication you are taking might be altered by the CaD study pills. Below are a few examples of common medications.

Bisphosphonates: Bisphosphonates are drugs used to treat osteoporosis. Alendronate (Fosamax®) and residronate (Actonel®) are two bisphosphonates currently approved by the Food and Drug Administration (FDA). Calcium (or almost anything other than water) may block the absorption of these drugs. The typical routine for taking Fosamax or Actonel is to take the drug first thing in the morning, after an overnight fast, with water only. Food, calcium and other medications should not be taken for at least 30 minutes afterwards. If you are taking either of these medications, it is important that you follow the instructions given to you.

Thyroid: Calcium may interfere with the absorption of thyroid medication; for example, Synthroid. It is best that you take your CaD study pills at least 4 hours before or after you take your thyroid medication.

Vitamins/Supplements

Iron: Short-term studies have shown that calcium may lower the body's ability to absorb iron. However, long-term studies have not shown an effect of calcium on iron absorption, possibly because the body adapts to the two substances being absorbed at the same time. In short, it probably doesn't matter if you take an iron supplement or multivitamin that contains iron with your CaD study pills.

Chewable Tablets vs. Swallowable Pills

"Other than being swallowable, are these study pills the same as the chewable tablets?"

If you are assigned to take active CaD study pills, the swallowable ones contain exactly the same amount of calcium (500 mg each) and vitamin D (200 IU each) as the chewable tablets. If you are assigned to the placebo (inactive) group, the swallowable study pills are also essentially the same as your chewable tablets.



Figure F.3.15
CaD Handbook, con't

CALCIUM/VITAMIN D HANDBOOK

11

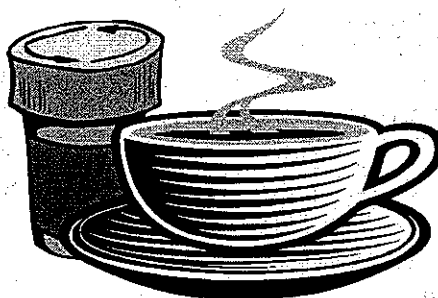
"Will changing to the swallowable study pills make my symptoms (like constipation, bloating, stomach upset) go away?"

Some women do tolerate one type of study pill better than the other. Because the swallowable study pills have exactly the same amount of calcium as the chewable ones, your symptoms may not change even if you switch to the swallowable study pills. However, you are always welcome to switch back during the study. There are also steps that you can follow to see if switching study pills can help your symptoms. Please read through the suggestions for relieving symptoms that were offered earlier in this handbook. As always, the clinic staff will continue to ask you about your symptoms to make sure it is still safe for you to continue in the CaD Program.

Other Common Questions

"Why do I bring my empty/remaining pill bottles into the clinic each year?"

It is important to collect all remaining study pills every year. We scan the bottles you return using the bar code so that we can keep track of our supply of pill bottles. This is important to keep complete records for all study participants. We are also able to properly dispose of any unused study pills.



"I had to stop taking my study pills because of an illness, but I would like to restart my pills. Can I do that and how would I do that?"

If you needed to stop your study pills for a medical, personal or other reason, it may be possible to restart your study pills. In order to determine if it is ok for you to restart your study pills, please call your WHI clinic and ask. Restarting your study pill involves coming into the clinic for a brief visit to get more study pills. Even if you have not taken study pills in some time, it may be possible for you to restart. Call your WHI clinic to see if restarting study pills is an option for you.

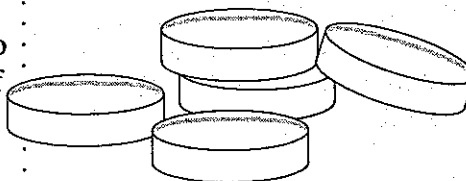
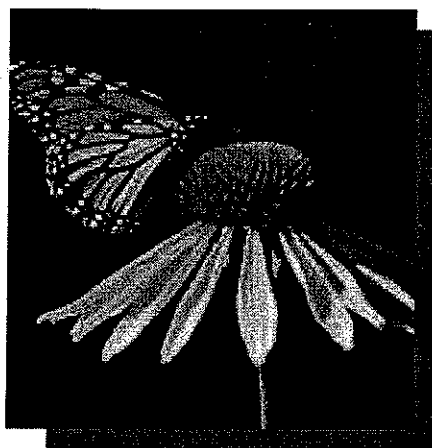


Figure F.3.15
CaD Handbook, con't

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THE WOMEN'S HEALTH INITIATIVE



Where Do We Go From Here?

Your contributions to the WHI Calcium and Vitamin D Program are appreciated. Your dedication is crucial so that we can answer remaining questions about the role of calcium and vitamin D in women's health. It is so important that you continue to take your study pills every day and come to all of your clinic visits (*remember to bring your empty or remaining pill bottles with you*). Every WHI woman's participation is invaluable to making sure that the CaD Program is a success!

Figure F.3.15
CaD Handbook, con't

More/Further Questions?

Please contact your WHI Clinical Center. The staff will be glad to answer any further questions or discuss other concerns that you may have.

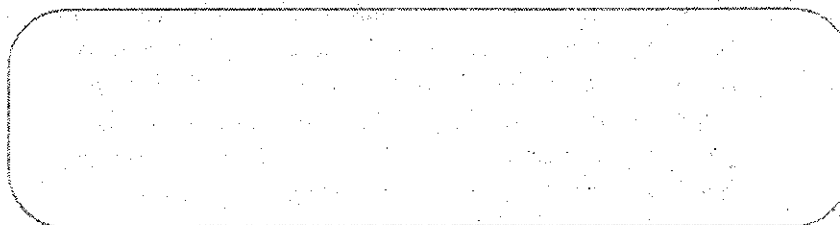


Figure F.3.15
CaD Handbook, con't



**Thank you for your continued participation
in the Women's Health Initiative.**

**Future generations of women
will be grateful for your contribution
to this important research!**

CaD Handbook-English, Ver: 1, 11/1/02

F.4 Provider Materials

Figure F.4.1
Chart Labels

1

This woman has been randomized to the WHI HRT, a placebo-controlled trial of 2 hormone replacement therapies to test their potential effect on coronary heart disease:

Women with an intact uterus – 0.625 mg/day conjugated equine estrogens (CEE) + 2.5 mg/day medroxy progesterone or placebo.

Women without a uterus – 0.625 mg/day CEE or placebo.

Please contact the clinic below if major changes in therapy or health status should occur, or if you have questions about this patient's WHI participation.



(Please affix clinic address/phone here.)

P204a\1-18-95

2

This woman has been randomized to the WHI Dietary Modification, a trial of low-fat, high fruits, vegetables and grains eating pattern, compared with a usual eating pattern to test the potential effect on breast and colorectal cancer incidence.

Please notify the clinic below if major changes in therapy or health status should occur, or if you have questions about this patient's WHI participation.



(Please affix clinic address/phone here.)

P204b\10-1-94

3

This woman has been randomized to the WHI Ca/Vit D, a placebo-controlled trial of Calcium and Vitamin D supplementation to test the potential effect on osteoporotic fractures.

Please notify the clinic below if major changes in therapy or health status should occur, or if you have questions about this patient's WHI participation.



(Please affix clinic address/phone here.)

P204c\10-1-94

4

This woman has been randomized to the WHI Observational Study, an evaluation of women's general health and chronic disease risk, particularly for cardiovascular, cancer, and osteoporotic related diseases.

Please notify the clinic below if major changes in therapy or health status should occur, or if you have questions about this patient's WHI participation.



(Please affix clinic address/phone here.)

P204d\10-1-94

F.5 Close-out Materials

Figure F.5.1
Health Screening Guidelines Handouts



GENERAL HEALTH SCREENING GUIDELINES FOR WOMEN OVER 50

These guidelines are for women who have an average risk for most diseases. Your health care provider will discuss the timing of each test based on your individual health care needs.

SCREENING TEST	USED TO	GENERAL RECOMMENDATION	COMMENTS
Breast self-exam	Detect breast tumors	Monthly	
Breast exam by a health care provider	Detect breast tumors	Annually	
Mammogram	Detect breast tumors too small to feel with breast self-exam	Every 1-2 years	
Pap smear	Detect cervical cancer	Every 1-3 years	Women with 3 normal tests in a row are at low risk; women over age 65 may be able to have less frequent testing (or even stop after age 70).
Pelvic exam	Examine uterus and ovaries for size, position, and possible growths	Annually	
Blood pressure	Detect high blood pressure (hypertension)	Every 1-2 years	Check more often if reading is over 130/85.
Blood cholesterol test	Measure total cholesterol and HDL and LDL cholesterol ("good" and "bad" cholesterol)	Every 5 years	Test more often if: total cholesterol is over 200, the ratio of Total Cholesterol to HDL (TC:HDL) is over 4, or if you gain a lot of weight.
Fast occult blood test	Detect hidden blood in stools, which may indicate colon or rectal cancer	Annually	All abnormal tests should be evaluated with a colonoscopy. Should not be the only screening test used to detect colorectal cancer.
Digital rectal exam	Detect polyps (growths), hemorrhoids, or blood in the rectum	Every 5-10 years with screening sigmoidoscopy or colonoscopy	Should not be the only screening test used to detect colorectal cancer.
Sigmoidoscopy	Detect colorectal cancer, polyps, or other intestinal problems in the lower colon or rectum	Every 5 years	Women at high risk may need to be tested more often. All abnormal tests should be evaluated with a colonoscopy.
Colonoscopy	Detect colorectal cancer, polyps, or other intestinal problems throughout the colon and rectum	Every 10 years	Provides an opportunity to visualize, sample, and/or remove abnormal lesions (changes).
Bone mineral density	Detect osteoporosis	Age 50-64, if at high risk Age 65 or over: all women	The need for repeat testing is based on initial bone density score and determined for each individual.

Health Screening Guidelines.doc 8/1/04

Figure F.5.2
Certificate of Appreciation

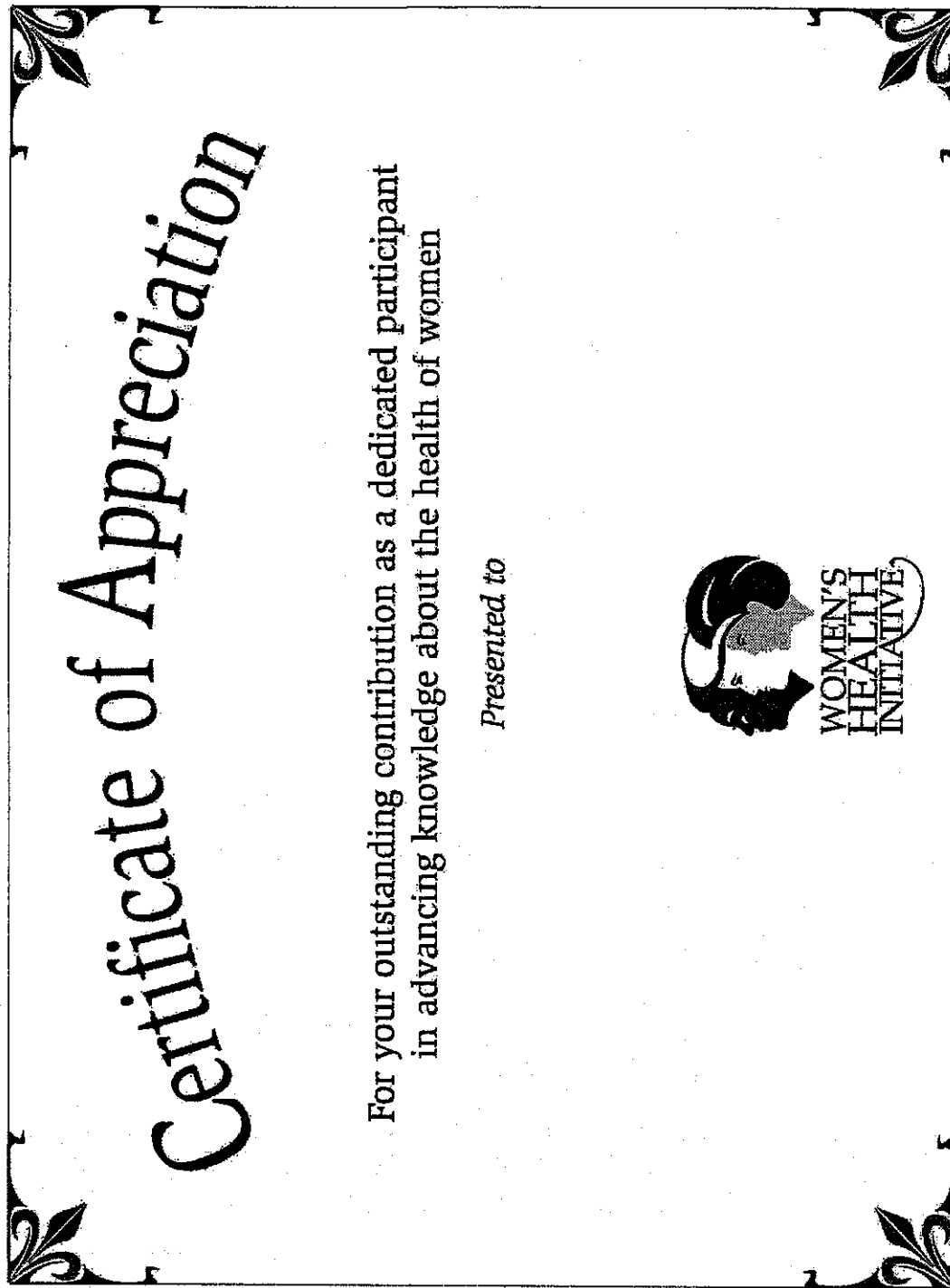


Figure F.5.3
WHI Dietary Study Summary

WHI Dietary Study Summary



Thank you for your many years of participation in the WHI Dietary Study. While we are all waiting for the results of the Dietary Study, we thought that you might be interested in seeing how the goals of the WHI Dietary Study compare to current national dietary guidelines for the public. As you can see in the table below, there are many similarities between the two eating patterns.

WHI Dietary Study Goals	National Dietary Guidelines for the Public*
Total fat 20% of total calories 7% or less of total calories as saturated fat**	Total fat 20-35% of total calories Less than 10% of total calories as saturated fat
Fruits and/or vegetables 5 or more servings daily	Fruits and/or vegetables 5 or more servings daily
Grains 6 or more servings daily**	Grains 6 or more servings daily, especially whole grains

* Based on guidelines from: USDA Dietary Guidelines for Americans (2000) and the Food & Nutrition Board of the Institute of Medicine (2002).

** The WHI Dietary Study had a goal for saturated fat, but Dietary Change participants were not asked to record their intake of saturated fat intake because it usually drops as total fat is reduced. Whole grains were encouraged as part of a healthy eating pattern, but they were not a specific study goal.

We will mail the study results to you as soon as all the data have been analyzed. This will be in early 2006.

Your personal health care providers, including a registered dietitian, can provide specific dietary advice or counseling, if you are interested. For help in finding a registered dietitian in your local area, call the **American Dietetic Association Consumer Hotline (800-366-1655)**.

The *WHI Dietary Study Frequently Asked Questions* handout, in your close-out packet, offers some additional ideas for nutrition resources.

Turn page over for more information.....

What did the WHI low-fat eating pattern look like?

Participants in the Dietary Change group were free to make their own choices based on the WHI dietary goals, as well as, individual and cultural preferences. Below are a few examples of food choices women in the Dietary Change group made to eat low-fat.

Morning:

Fruit or vegetable juice
(100% juice) - $\frac{3}{4}$ cup
Oatmeal - 1 cup
Raisins - 2 tablespoons
Skim milk - 1 cup
Coffee, tea or water

**Morning:**

Fruit or vegetable juice
(100% juice) - $\frac{3}{4}$ cup
Poached egg - 1 large
Whole wheat toast - 1 slice
Light tub margarine - 1 tsp
Skim milk - 1 cup
Coffee, tea or water

Afternoon:

Tuna salad sandwich: made with water-packed tuna and 2 Tb. low-fat mayonnaise on 2 slices of whole wheat bread with lettuce and tomato
Pretzels - 6 twists
Apple - 1 medium
Skim milk - 1 cup

**Afternoon:**

Bean burrito (made with plain 8" flour tortilla, fat-free refried beans; no meat)
Tomato salsa - $\frac{1}{4}$ cup
Carrot and celery sticks - $\frac{1}{2}$ cup
Gingersnaps - 4 small cookies
Skim milk - 1 cup

Evening:

Tossed green salad (1 cup) with 1 Tbsp. reduced-fat salad dressing
Oven roasted chicken breast
(4 ounces); baked without skin
Mashed sweet potatoes - $\frac{1}{2}$ cup
(no fat added)
Steamed broccoli - $\frac{1}{2}$ cup (no fat added)
Whole grain roll - 1 small with
1 tsp. light tub margarine
Sorbet - $\frac{1}{2}$ cup
Coffee, tea, or water

Evening:

Marinated cucumber salad (cucumbers and onions marinated in seasoned rice vinegar) - $\frac{1}{2}$ cup
Stir-fry - $1\frac{1}{2}$ cups (1 cup vegetables and 2 oz. lean beef cooked in 1 tsp. oil)
Steamed rice - 1 cup (no fat added)
Angel food cake - $\frac{1}{8}$ of 10" diameter with
 $\frac{1}{2}$ cup sliced fruit
Coffee, tea, or water

Snack (anytime):

Grapes - $\frac{1}{2}$ cup
Fig bar cookies - 2 small cookies

Snack (anytime):

Tomato juice (100% juice) - $\frac{3}{4}$ cup
Plain air-popped popcorn - 3 cups
(no fat added)



Figure F.5.4
WHI Dietary Study Frequently Asked Questions

WHI Dietary Study Frequently Asked Questions

Q: What question is the WHI Dietary Study designed to answer?

A: The WHI Dietary Study is designed to answer whether a low-fat eating pattern that is high in fruits, vegetables, and grains reduces the risk of breast cancer, colorectal cancer, and heart disease in postmenopausal women.

Q: What other answers might the WHI Dietary Study results provide?

A: Thanks to you, the WHI Dietary Study will add more than any previous study in history to the knowledge of diet and health in postmenopausal women. For example, WHI scientists will be able to explore the health effects of combining the WHI low-fat eating pattern with hormone therapy as well as calcium and vitamin D supplementation. Scientists will be able to do this because some women in the Dietary Study were also in the Hormone Program and/or the Calcium and Vitamin D Study. In fact, some women were in all three WHI studies. Your generous participation will make it possible to explore the health effects related to all three study interventions.

Q: What eating changes were women in the Dietary Change group asked to make?

A: Women in the Dietary Change group were asked to lower their fat intake and increase their servings of fruits, vegetables, and grains. Specifically, women in the Dietary Change group received a WHI fat gram goal to help them eat about 20% of their calories from fat. They were also asked to eat 5 or more servings of fruits and/or vegetables and 6 or more servings of grains each day.

Q: Were women in the Comparison group of the WHI Dietary Study asked to change what they eat?

A: No. Women in the Comparison group were not asked to make any changes in what they usually eat.

Q: Why is the Comparison group so important to the WHI Dietary Study?

A: The Comparison group makes it possible to compare the results for the group that is changing its diet to a similar group of women who are not making study-related changes. In this way, WHI scientists can account for gradual diet changes that women may make for reasons not linked to the study. Scientists can also consider changes that happen normally as people get older. Without the Comparison group, there would be no WHI Dietary Study!

Q: How and when will I learn if the WHI eating pattern reduces the risk of developing breast cancer, colorectal cancer, and heart disease in postmenopausal women?

A: WHI scientists will compare disease rates between the Dietary Change and Comparison groups after all participants have completed their close-out visit (March 31, 2005). This comparison will let us see if the WHI eating pattern reduced the risk of developing breast cancer, colorectal cancer, and heart disease. We will mail the study results to you after all the data have been analyzed. This will be in early 2006.

Q: Will the WHI Dietary Study results contribute to future national dietary guidelines for the public?

A: Yes. The WHI Dietary Study results will add to what we currently know about the overall health benefits and risks of a low-fat eating pattern that is high in fruits, vegetables, and grains. These results will be considered with other scientific evidence when nutrition experts determine future national dietary guidelines for the public. The *USDA Dietary Guidelines for Americans* and *USDA Food Guide Pyramid* are examples of national dietary guidelines for the public that are based on the most current scientific and medical knowledge available. The WHI Dietary Study results will be a part of the evidence considered when these guidelines are reviewed and updated in the future.

Q: What should I eat?

A: Your personal health care providers, including a registered dietitian, can offer guidance about an eating pattern that is right for you. Contacting your personal health care providers for dietary guidance is particularly important if you have a diet-related health condition such as diabetes, heart disease, or are above or below a healthy weight. The Dietary Summary included in your close-out packet provides a snapshot of current national dietary guidelines for the public and how they compare to the goals of the WHI Dietary Study. There are many similarities between the two eating patterns. When the WHI Dietary Study results become available in early 2006, you can also consider them in light of your personal needs to further guide your food choices.

Q: If I want more information about nutrition, where can I find it?

A: The American Dietetic Association (ADA) is the nation's largest organization of food and nutrition professionals. The ADA has a Consumer Hotline (1-800-366-1655) where you can listen to brief pre-recorded nutrition messages or get help finding a registered dietitian in your local area. You can find additional food and nutrition information at the ADA website (www.eatright.org). The U.S. government has many health-related resources. For example, the www.healthierus.gov website offers information about a variety of nutrition topics such as healthy eating, food label reading, the *USDA Dietary Guidelines for Americans*, and the *5 A Day for Better Health* program.

Figure F.5.5
CaD Fact Sheet



Calcium/Vitamin D Fact Sheet

Calcium is essential for the health of your bones and for other important body functions that involve the nerves, muscles, heart, and blood clotting. Most of the calcium in your body is stored in your bones. When dietary calcium is too low, your body will take calcium from your bones and use it for these other body functions.

Most women get less than half of the daily recommended amount of calcium. The National Academy of Sciences currently recommends that adults 50 years of age and older get a minimum of 1200 mg of calcium each day. One way to meet this daily goal is to eat a variety of foods that contain calcium. The table on page 2 lists common foods that contain calcium.

Calcium Supplements

If you cannot get enough calcium in your diet, your health care provider may suggest you take a calcium supplement. There are many types on the market – calcium carbonate, calcium phosphate, and calcium citrate. The supplement that best meets your needs should be chosen based on how well you tolerate it, how convenient it is to take, and its cost and availability. Try to select a calcium supplement that has a known brand name with proven reliability (label may say “purified” or “USP”). Supplements vary in the amount of “elemental calcium,” which refers to the actual amount of calcium the supplement contains. In order to increase absorption of calcium and decrease the risk of side effects such as gas, bloating, and constipation, calcium supplements should be taken in small doses of no more than 500 mg several times a day with plenty of fluids. Talk to your health care provider about the need for a calcium supplement, and if so, the type and amount you should be taking.

Vitamin D

Vitamin D is also important for bone health and plays a key role in helping the body absorb calcium. Most of the vitamin D in our body is made in the skin following exposure to sunlight. A 10-15 minute walk in the sunshine two to three times a week is usually enough to meet the body's need for vitamin D. Major food sources of vitamin D include fortified dairy products such as milk or yogurt, egg yolks, and liver. It is also commonly found in calcium supplements. In some cases, the body cannot make enough vitamin D, which can occur as women get older or if they are housebound and do not get out in the sun. The recommended daily intake of vitamin D is 400-800 international units (IU).

Common Calcium-Containing Foods

FOOD SOURCES	Calcium (mg)	% DV*
Dairy		
Cheddar cheese, shredded, 1 ½ oz.	306	31%
Yogurt, plain, low fat, 8 oz.	300	30%
Milk, non-fat, 8 fl oz.	302	30%
Milk, reduced-fat (2% milk fat), no solids, 8 fl oz.	297	30%
Milk, whole (3.25% milk fat), 8 fl oz.	291	29%
Milk, buttermilk, 8 fl oz.	285	29%
Milk, lactose reduced, 8 fl oz.	285-302	29-30%
Cottage cheese, 1% milk fat, 2 cups unpacked	276	28%
Mozzarella, part skim, 1 ½ oz.	275	28%
Frozen yogurt, vanilla, soft serve, ½ cup	103	10%
Ice cream, vanilla, ½ cup	85	8.5%
Sour cream, reduced fat, cultured, 2 tbsp.	32	3%
Cheese, cream, regular, 1 tbsp.	12	1%
Breads/Cereals		
Ready to eat cereal, calcium fortified, 1 cup	100-1000	10-100%
Tortilla, corn, ready to bake/fry, 1 medium	42	4%
Tortilla, flour, ready to bake/fry, one 6" diameter	37	4%
Bread, white, 1 oz	31	3%
Bread, whole wheat, 1 slice	20	2%
Beverages		
Orange juice, calcium fortified, 6 fl oz.	200-260	20-26%
Pudding, chocolate, instant, made w/2% milk, ½ cup	153	15%
Breakfast drink, orange-flavor, powder prepared w/water, 8 fl oz.	133	13%
Soy beverage, calcium fortified, 8 fl oz.	80-500	8-50%
Vegetables		
Turnip greens, boiled, ½ cup	99	10%
Kale, raw, 1 cup	90	9%
Kale, cooked, 1 cup	94	9%
Chinese cabbage, raw, 1 cup	74	7%
Broccoli, raw, ½ cup	21	2%
Miscellaneous		
Sardines, canned in oil, with bones, 3 oz.	324	32%
Tofu, firm, w/calcium, ½ cup**	204	20%
Salmon, pink, canned, solids with bone, 3 oz.	181	18%
Tofu, soft, w/calcium, ½ cup**	138	14%

* Daily Values were developed to help people decide if a serving of a food contains a lot or a little calcium. The DV for calcium is 1000 mg). The percent Daily Value on the nutrition facts panels of food labels tells you what percentage of the DV is provided in one serving. For example, if you consumed food that contained 300 mg of calcium, the calcium DV on the food label would be 30%.

** Calcium values for tofu are only for tofu that is processed with a calcium salt. Tofu processed with a non-calcium salt will not contain significant amounts of calcium.

